



**TARGET PRODUCT PROFILE of NON-INVASIVE and MINIMALLY-INVASIVE
GLUCOSE SELF-MONITORING DEVICES for LOW- and MIDDLE-INCOME
COUNTRIES: a QUALITATIVE STUDY in KYRGYZSTAN, MALI, PERU and TANZANIA**

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A project of:

FIND 
Diagnosis for all

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Addressing the Challenge and Constraints
of Insulin Sources and Supply

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TARGET PRODUCT PROFILE of NON-INVASIVE AND MINIMALLY-INVASIVE GLUCOSE SELF-MONITORING DEVICES for LOW- and MIDDLE-INCOME COUNTRIES: A QUALITATIVE STUDY in KYRGYZSTAN, MALI, PERU and TANZANIA

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List of Abbreviations

CI	Couple Interviews
FGD	Focus Group Discussions
HCW	Health Care Workers
LMIC	Low-and-Middle-Income Countries
LSS	Lead Social Scientist
NI-MI-GMD	Non-invasive and Minimally-invasive Glucose Monitoring Devices
PAR	Participatory Action Research
PLWD1	Persons Living with Type 1 Diabetes
PLWD2	Persons Living with Type 2 Diabetes
R&D	Research & Development
SMBG	Self-Monitoring of Blood Glucose
SSI	Semi-Structured Interviews
TPP	Target Product Profile
VoIP	Voice over the Internet Protocol software

BACKGROUND

A target product profile (TPP) defines the characteristics and requirements of a target product that is aimed at a particular disease or condition. TPPs set research and development (R&D) targets for funders and developers, and can provide guidance on product selection to health system administrators, healthcare professionals, and patients and caregivers.

In recent years, numerous non- and minimally-invasive glucose self-monitoring technologies (NI-MI-GMD) have entered the R&D pipeline, largely from developers in high-income countries with the respective local user requirements in mind. The needs and preferences of users of NI-MI-GMD in low- and middle-income countries (LMIC) have been given little consideration, which may result in suboptimal products for people living with diabetes in LMIC, considering cultural, environmental and economical differences between high-income countries and LMIC.

In tackling this dearth of knowledge, we carried out a multi-country, mixed-methods, qualitative study with the main aim to capture the characteristic and requirements of NI-MI-GMD for users, their care providers and healthcare professionals in LMIC. The findings of our study are to feed a TPP for NI-MI-GMD development process.

1. METHODOLOGY: An Overview

1.1 Design, sites, and study groups

This was a mixed-methods, exploratory, qualitative study in design that considered part of the guidance to design and carry out qualitative inquiries in LMIC provided by Expósito Verdejo¹, Kielmann et al.,² and Wuest³. The study was conducted in four countries, and in the cities where partner organisations operate. Namely, in Bishkek (Kyrgyzstan), Bamako (Mali), Lima (Peru), and Dar es Salaam (Tanzania). Country organisations were selected by the sponsors (FIND; Health Action International) due to their trajectory in the field of diabetes care.

Five study groups were targeted: diabetes care providers (i.e., nurses and/or physicians) (hereafter HCW); persons living with type 1 diabetes (PLWD1); persons living with type 2 diabetes (PLWD2); caregivers of minors living with type 1 diabetes; adolescents living with type 1 diabetes. Willingness to provide consent for participation and fluency with local vernaculars were inclusion criteria for participation. Exclusion criteria were: unwillingness to provide informed consent (for HCW, PLWD1, PLWD2, and caregivers), or parental consent and informed assent (for caregivers and adolescents invited to participate in an CI).

Semi-structured interviews (SSI), couple interviews (CI), focus group discussions (FGD) and participatory action research (PAR) sessions were conducted. In the pursuit of data saturation, in each country, 42 SSI, six CI (each with a caregiver and an adolescent), seven FGD (with up to seven discussants each) and one PAR session (with 42 attendees) were proposed (Table 1).

Each country organisation organised a team of field researchers who, under the guidance of the Principal Investigator in the country and of FIND's Lead Social Scientist, were responsible for the obtention of ethical and administrative permissions to conduct the research; the conduct of the pilot of data collection instruments, and their adaptation to local contexts; the sampling and recruitment of participants; the conduct of SSI, CI, FGD and PAR sessions; and the preparation

¹ Expósito Verdejo, M. *Diagnóstico Rural Participativo: Una guía práctica*. Santo Domingo: Centro Cultural Poveda; 2003.

² Kielmann, K., Cataldo, F., & Seeley, J. (2012). *Introduction to qualitative research methodology: a training manual*. United Kingdom: Department for International Development (DfID).

³ Wuest, J. (1995). Feminist grounded theory: an exploration of the congruency and tensions between two traditions in knowledge Discovery source. *Qualitative Health Research*, 5, 125-37.

of verbatim transcription of records for analysis. The field researchers participated in online and in-person pre-fieldwork revision of data collection instruments and of study-specific procedures, led by FIND's Lead Social Scientist (LSS).

Table 1 - Proposed number and type of key informants per research method for each country

Populations	Key informants			Total per country
	Combined FGD/PAR	SSI	CI	
1. Diabetes care providers	12	12	-	24
2. PLWD1	12	12	-	24
3. PLWD2	12	12	-	24
4. Caregivers of minors living with type 1 diabetes	6	6	6	18
5. Adolescents living with type 1 diabetes	-	-	6	6
Total participants per country	42	42	12	96
Total data generation encounters per country	7 FGD/1 PAR	36	6	51

A mix of purposive and snowball techniques were used. At first, gender-disaggregated lists of potential study informants, using a variety of sources (e.g., training attendance lists, organisation reports, websites of local associations of PLWD, HCW councils, etc.) were prepared. Balance in gender representation was pursued. Using these lists, the field researchers approached in-person or over the phone all pre-identified informants. Reached individuals received an explanation on the study aim, leading organisations, study procedures, on what would be expected of them, and, if applicable, on the incentives they would receive. If they expressed interest in the study, they were invited to either partake in a joint FGD/PAR session or in an SSI (for HCW, PLWD1, PLWD2, and caregivers), or in a CI (for caregivers and adolescents). Depending on their preference, a date for the data generation encounter was arranged. Subsequently, snowball sampling was used: Individuals invited to a data generation encounter were asked to suggest the names of persons who, in their opinion, could be approached as potential informants.

At the scheduled date, the interviewers verified that the individuals had read the consent documents, and understood its content. The interviewers would assist with reading the consent documents when individuals reported a visual impairment. If individuals had poor literacy, the interviewers asked them to identify a witness who could read the consent documents to them. HCW, PLWD1, PLWD2 and caregivers who consented to participate in an FGD/PAR or in an SSI/CI were asked to sign two copies of the informed consent forms. Caregivers and adolescents who consented to participate in an CI were asked to sign two copies of the parental consent (for the adult) and of the informed assent (for the adolescent). All individuals recruited as study informants took one signed copy home.

After the informed consent process, a personal unique identifier was entered on each signed document. This identifier was the only means to link any informant's consent document to their socio-demographics and to the recordings and transcripts of their data collection encounters.

1.2 Data collection techniques

HCW, PLWD1, PLWD2 and caregivers were invited to partake in SSI. Caregivers and adolescents were invited to partake in CI. Whilst any caregiver could participate in SSI, the caregivers invited to partake in CI had to be the legal guardians of the adolescents with whom they would discuss the study topic during the CI. SSI/CI informants were interviewed at their

date of convenience, and either in a private venue chosen by the country organisations or via any VoIP software of their preference.

The SSI/CI guide consisted of a range of open-ended questions grouped in themes of interest to inform the TPP for NI-MI-GMD (Appendix 1). During the SSI/CI, the interviewers posed, in a theme-by-theme manner, the questions included in the SSI/CI guide. The interviewers used visual aids to help informants with insufficient knowledge of NI-MI-GMD to understand the type of glucose monitoring devices of interest in this study⁴.

A minimum of 42 informants from HCW, PLWD1, PLWD2 and caregivers groups were invited to participate in an FGD/PAR session. Where feasible, FGD/PAR took place the same day and in the same private venue chosen by the country organisations. In each country, it was proposed to start the FGD/PAR session by conducting one FGD with each of the study groups (counting on a maximum of seven informants per FGD). These first FGD were conducted by a moderator and a note-taker in a private room. The FGD guide followed the same structure of the SSI/CI guide (Appendix 1) with the aim to compare if, as a result of social desirability or group pressure, the FGD informants' narratives could diverge, and in what form, from the SSI/CI informants' narratives. After the conduct of these morning FGD groups, the discussants were to move to a larger room where they would meet the discussants of the afternoon FGD groups (i.e., one per study group, expecting a maximum of seven informants per FGD).

In this room, a total of two PAR exercises would be performed. To carry out the exercises, the informants sat at separate tables with the same informants with whom they were to partake in the FGD. The first exercise used the 'piling-up' techniques to encourage the informants to identify what would be their preferences regarding the characteristics and requirements that developers of NI-MI-GMD for LMIC should prioritize (Appendix 2).

The second exercise used the 'matrix' technique to encourage the informants to discuss the utility of eight different NI-MI-GMD that were presented to them at the start of the PAR session (Appendix 2). The exercises were led by a different moderator at each table. The informants were asked to engage in each exercise in a participative, confidential, and collaborative manner. The moderators recorded the discussions in each separate table, noted key expressions or emerging considerations for analysis, and took photographs of every flipchart, post-it, MS Word document, or drawing prepared by the group members. After the finalisation of the two exercises, the informants who participated in the morning FGD left the venue. The informants invited to participate in the afternoon round of FGD moved to private rooms. The afternoon FGD were conducted using the same procedures and FGD guide as in the morning FGD.

Table 2 shows which characteristics of a TPP for NI-MI-GMD were intended to be explored with the recruited informants in each of the data collection encounters planned for this study.

1.3 Data processing and analysis

Socio-demographic data was collected prior to the start of data collection. Verbatim transcripts of SSI/CI/FGD were prepared. The transcripts from Kyrgyzstan and Tanzania were translated into English. One non-verbatim transcript per each discussion group in each PAR session was prepared. The PAR transcripts included photographs of the exercises, and a summary of the

⁴ Eight devices were shown to the study informants. Namely: the GBS Inc.[™] saliva glucose sensor (<https://gbs.inc/the-saliva-glucose-biosensor/>); the GlucoTrack[®] (<http://www.glucotrack.com>); the glucoWISE[®] (<https://gluco-wise.com>); the Cnoga Medical TensorTip Combo Glucometer[®] (<https://www.cnogacare.co/cog-hybrid-glucometer>); the Alertgy[™] non-invasive wrist band glucose sensor (<https://www.alertgy.com/technology/>); the NovioSense[™] non-invasive tear glucose sensor (<http://noviosense.com>); the FreeStyle Libre 3[®] (<https://www.freestyle.abbott/us-en/home.html>); and the K'Watch Glucose[®] (<https://www.pkvitality.com/ktrack-glucose/>).

discussions held around the realisation of the exercises. The country teams shared all transcripts with the LSS. All socio-demographic data, informed consent forms, and informants' narratives were managed in accordance with local regulations for personal data protection.

Content analysis was the approach used for data analysis. All transcripts were coded in Quirkos® or manually as per a predefined MS-Excel® matrix which included a set of labels that mirrored the structured dimensions > characteristics > requirements of the draft TPP for NI-MI-GMD handled by FIND (Table 2). Content analysis was deductive, although it allowed for inductive coding: any new concepts emerging from the data were incorporated to the set.

Table 2 - Characteristics described in the TPP for NI-MI-GMDs

Characteristics*	SSI, CI, and FGD	PAR sessions
Dimension: Scope		
Intended Use	√	--
Target Population/Condition	√	--
Target Operator	√	--
Infrastructure level (Internet, water, electricity...)	√	√
Dimension: Device		
Physical area of measurement	√	√
Attachment to the body	√	√
Application to the body	√	√
Degree of invasiveness	√	√
Sample type	√	√
Measurement cycle	√	√
Additional equipment or consumables required	√	√
Duration of use before any hardware needs to be replaced	√	√
Interchangeability	√	--
Dimension: Utility Requirements		
Data display	√	√
Alerts and user guidance	√	√
Connectivity device to reader or other equipment	√	√
Data transfer frequency	√	--
Data management	√	--
Power source	√	√
Operating temperature	√	√
Storage temperature	--	√
Dimension: Performance and Results		
Accuracy	√	√
Calibration	√	√
Results Format	√	--
Dimension: Purchasing Considerations		
Price	√	√
Business model	√	√

1.4 Ethics statement

The study protocol was approved by Research Ethics Committees in each country. Where applicable, informants received compensation for their time and transport.

2. INFORMANTS' CHARACTERISTICS

A total of 29 FGD, 144 SSI, and 24 CI were conducted (Table 3). Seven FGD were conducted in Kyrgyzstan, Mali and in Tanzania, whilst eight FGD were conducted in Peru. In Kyrgyzstan and in Tanzania, the PAR session (with seven study groups) was conducted in a single day. In Mali and Peru, two PAR sessions were conducted in two different days due to the unfeasibility to decide on a date that could be convenient for all study groups.

In total, 383 persons participated as informants in these data collection encounters (Table 3). Of these 383, 251 (65.5%) were women. Ninety (23.5%), 100 (26.1%), 92 (24.0%), and 76 (19.8%) were HCWs, PLWD1, PLWD2, and caregivers, respectively. Eighteen (4.7%) female and seven (1.8%) male adolescents participated in CI with their caregivers. More than half of the sample (57.7%) were aged between 26 and 55 years old. Just 10 informants (3.6%) were born in a country other than the study country. In terms of education, eight (2.1%) informants in Mali reported that they had no completed education. Tanzania was the country with the highest representation of informants with primary studies only ($n=29$, 7.6%). Completion of secondary studies ranged from 8.9% of the total ($n=34$) in Kyrgyzstan, to 5.7% ($n=22$) in Mali and in Peru. See Table 4 for a summary of informants' self-reported insulin regimes.

Table 3 - Sex-disaggregated informants' characteristics, by country

Country:		Kyrgyzstan		Mali		Peru		Tanzania		TOTAL	
Variable	Sex: (N):	F (79)	M (19)	F (51)	M (42)	F (63)	M (34)	F (58)	M (37)	F (251)	M (132)
Study group	HCW	24	1	7	13	16	5	18	6	65	25
	PLWD1	18	5	15	12	11	14	12	13	56	44
	PLWD2	14	10	16	7	11	12	15	7	56	36
	Caregivers	17	2	8	9	21	1	10	8	57	20
	Adolescents	6	1	5	1	4	2	3	3	17	7
Encounters	SSI	33	9	22	19	26	15	29	14	110	57
	CI	10	2	8	4	9	3	6	6	33	15
	FGD only	0	0	0	0	0	0	0	0	0	0
	PAR only	2	1	0	0	0	0	0	0	2	1
	FGD+PAR	34	7	20	19	28	16	23	17	105	59
SSI, FGD AND PAR		0	0	1	0	0	0	0	0	1	0
Age groups	<18	6	1	4	1	4	2	3	3	18	7
	18-25	11	3	11	4	4	8	7	8	33	23
	26-35	11	2	8	16	19	4	10	7	48	29
	36-45	20	0	9	8	15	4	11	4	55	16
	46-55	13	2	7	6	13	6	18	8	50	22
	56-65	9	11	10	5	6	7	7	5	32	28
	>65	9	0	2	2	2	3	2	2	15	7
Country of birth	Same country	75	18	48	42	63	32	58	37	244	129
	Other country	4	1	3	0	0	2	0	0	7	3
Education	None	0	0	7	1	0	0	0	0	7	1
	1ary	3	2	17	4	1	0	18	11	39	17
	2ary	26	8	12	10	15	7	17	13	70	38
	Higher	50	9	15	27	47	27	19	11	131	74
	Not available	0	0	0	0	0	0	4	2	4	2

Table 4 - PLWD1, PLWD2 and adolescents' self-reported insulin regimes

Study groups: Country:	Adolescents				PLWD1				PLWD2				Total
	Kyrg*	Mali	Peru	Tanz#	Kyrg*	Mali	Peru	Tanz#	Kyrg*	Mali	Peru	Tanz#	
Type of insulin regimen													
Human insulin	-	4	-	4	5	25	4	21	22	20	2	13	120
Analogue insulin	7	1	5	-	17	-	13	-	-	-	5	-	48
Analogue / Human mix	-	-	-	-	3	-	-	-	-	-	-	-	3
Not reported/Does not know	-	1	-	2	-	3	8	4	-	3	15	8	44
Not on insulin	-	-	-	-	-	-	-	-	-	-	1	1	2

* Kyrg = Kyrgyzstan ; # Tanz = Tanzania

3. RESULTS

Unless otherwise indicated, results from the content analysis process that are described below were common across the four countries. Expressions in “*italics and quotation marks*” correspond to terms used by the study informants. The results are described in accordance with the structure of the draft TPP for NI-MI-GMDs (refer to Table 2 above). In reporting the findings in this section, general insights and isolated voices received the same consideration.

3.1. Prioritization of TPP dimensions and characteristics.

In total, 29 PAR discussion groups took place during the country PAR sessions: eight with HCWs, eight with PLWD1, eight with PLWD2, and five with caregivers. The PAR groups were asked to participate in a ‘piling-up’ exercise where they received a first set of five cards with the high-level dimensions of the TPP of NI-MI-GMD (Appendix 2), a second set of 16 cards with 16 basic characteristics that are considered in the TPP of NI-MI-GMD (and Appendix 2), and a third set of >60 cards which, grouped under each of the 16 characteristics described in the second set, suggested various requirements that could be considered for future NI-MI-GMD. The PAR groups were asked to discuss each set of cards separately, and to pile the cards up according to their own priorities and preferences.

Of the 29 groups, 12 and 10 groups chose *Performance and results* and *Purchasing considerations*, respectively, as the R&D dimensions of utmost importance to them (Table 5). *Utility* was only prioritized as the most important dimension by two groups in Peru.

Table 5 - PAR Results of category prioritization

DIMENSIONS	Kyrgyzstan (7 PAR groups)		Mali (7 PAR groups)		Peru (8 PAR groups)		Tanzania (7 PAR groups)		Total (29 PAR groups)	
	Average rating*	Number of ‘1s’	Average rating*	Number of ‘1s’	Average rating*	Number of ‘1s’	Average rating*	Number of ‘1s’	Average rating*	Number of ‘1s’
Device (Body)	4.57	-	3.57	1/7	3.5	1/8	2.71	1/7	3.6	3/29
Device (Technical)	3.29	-	3.29	1/7	3.25	2/8	4.57	-	3.6	3/29
Utility	3.14	-	3.86	-	2.5	2/8	3.71	-	3.3	2/29
Performance and Results	1.43	4/7	1.86	4/7	2.75	2/8	1.71	2/7	2.0	12/29
Purchasing Considerations	2.57	3/7	2.43	1/7	2.5	2/8	2.14	4/7	2.4	10/29

* The lower the rating, the higher in the groups’ piles the dimensions cards were put by the groups’ members.

Regarding the characteristics in the TPP of NI-MI-GMD, each group had to choose 10 of the 16 cards in the second set (Table 6). Once the 10 cards were chosen, the groups discussed how to pile them up according to what they thought was the pertinence or value of each characteristic. Of the 29 groups, 12 and 10 groups chose *Performance and results* and *Purchasing considerations*, respectively, as the R&D dimensions of utmost importance to them. The dimension *Utility* was only prioritized as the most important dimension by two groups in Peru. Of the 16 cards in the second set, *Infrastructure level* (chosen nine times), *Power source* (14), *Attachment to the body* (11), *Operating temperature* (11), and *Calibration* (10) were chosen by less than half of the PAR groups. Almost all groups chose *Alerts/User guidance* (26) and *Price/Purchasing characteristics* (27).

Based on their choices regarding the second set of cards, during the third part of the exercise, each group discussed only the requirement that pertained to the 10 characteristics they prioritized. The groups’ decisions regarding the third set of cards are described in the following sub-headings 3.2.1 through 3.6.2.

Table 6 - PAR results of characteristics prioritization

CHARACTERISTICS	Kyrgyzstan (7 PAR groups)		Mali (7 PAR groups)		Peru (8 PAR groups)		Tanzania (7 PAR groups)		Total (29 PAR groups)	
	Average rating	Number of times chosen	Average rating	Number of times chosen	Average rating	Number of times chosen	Average rating	Number of times chosen	Average rating	Number of times chosen
Infrastructure level (Internet, water, electricity...)	8	4	-	-	10.0	3	6.5	2	8.3	9
Physical area of measurement	7.8	4	7.3	7	6.3	4	4.6	7	6.3	22
Attachment to the body	8.0	1	6.6	4	4.3	3	4.7	3	5.5	11
Degree of invasiveness	5.8	5	5.8	4	5.0	5	4.8	6	5.3	20
Sample type	8.8	4	5.3	6	5.0	7	2.8	5	5.3	22
Additional equipment required	8.3	3	7.2	6	6.5	2	4.3	3	6.7	14
Duration of use	5.3	6	6.7	6	5.3	7	6.0	3	5.8	22
Measurement cycle	4.7	7	5.0	4	5.3	7	6.3	4	5.2	22
Data display	6.0	5	8.0	3	4.6	7	4.0	7	5.2	22
Connectivity / Data management	4.5	4	10.0	1	5.0	8	6.7	6	5.7	19
Alerts / User guidance	5.4	7	3.6	7	4.6	7	7.4	5	5.1	26
Power source	4.0	1	8.0	4	9.3	3	8.0	6	8.0	14
Operating temperature	9.0	2	7.0	3	9.0	2	5.0	4	7.0	11
Measurement accuracy	1.1	7	1.1	7	1.7	7	1.0	1	1.3	22
Calibration	6.0	5	10.0	1	2.0	2	10.0	2	6.4	10
Price and business model	3.7	6	3.0	7	3.1	8	5.5	6	3.7	27

* The lower the rating, the higher in the groups' piles the characteristics cards were put by the groups' members.

3.2. Scope

3.2.1. Intended Use.

Informants were asked the reasons why they would use NI-MI-GMD, and if they would appreciate seeing further functions in the NI-MI-GMD that glucose meters currently lack (Table 7). The majority would use, or recommend the use, of NI-MI-GMD to stop finger pricking.

Caregivers and HCW were especially concerned about the effect of finger pricking in children. Although most PLWD1 and PLWD2 also expressed that they want to stop finger pricking, there were a few adults in these study groups who expressed that they did not consider pricking such a painful procedure and that they would need to appreciate advantages other than avoidance of pain in NI-MI-GMD for them to decide that NI-MI-GMD is a worthy investment.

I would like the app to be functionally similar to Twitter. That is, you can make a private profile, keep your diary there, or you can open access for others to view, without the right to edit, only view. Then those who wished, who achieved good and stable glucose, could share their data with others about their diet and lifestyle.

(Kyrgyzstan, Male living with type 1 diabetes, 24 years old)

I think if they give me a bracelet for measuring blood glucose, this one without piercing, then I would wear it day-and-night.

(Kyrgyzstan, Female living with type 2 diabetes, 68 years old)

Irrespective of whether the option to avoid pain was considered appealing, informants from all study groups expressed that NI-MI-GMD should have a similar or inferior cost to glucose meters and test strips for them to switch to NI-MI-GMD to monitor their glucose levels. There were merely a few informants, especially among the caregivers, who said that they or their relatives would be willing to pay more to see how their children may eliminate finger pricking.

Table 7 - Intended use and expected functionalities

Findings from the SSI, CI, FGDs:*					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Stop finger pricking	58.2%	83.6%	90.9%	91.1%	81.4% (180)
Check glucose range	29.1%	29.1%	61.8%	35.7%	38.9% (86)
Anticipate hypo/hyper events	21.8%	49.1%	76.4%	53.6%	50.7% (112)
Act upon an acute emergency	21.8%	50.9%	67.3%	55.4%	49.3% (109)
Conciliate work and child care (for parents)	20.0%	7.3%	27.3%	21.4%	19.0% (42)
Use during recreational activities	18.2%	14.5%	27.3%	8.9%	17.2% (38)
Regulate diet	12.7%	10.9%	40.0%	19.6%	20.8% (46)
Regulate insulin or oral medication	30.9%	27.3%	54.6%	35.7%	37.6% (83)
Education (e.g., nutritional advices)	7.3%	-	16.4%	-	5.9% (13)
Reminders to take measurements	7.3%	7.3%	20.0%	19.6%	14.0% (31)
Check other parameters	18.2%	10.9%	23.6%	14.3%	16.7% (37)
Parameters for pregnant women (other than glucose)	-	7.3%	7.3%	12.5%	6.8% (15)
Measure ketones	5.5%	7.3%	7.3%	-	5.0% (11)
Test pregnancy	1.8%	-	-	-	0.9% (2)
If a person developed gestational diabetes	1.8%	-	1.8%	1.8%	1.4% (3)
Verify if a person has eaten	-	-	-	1.8%	0.5% (1)
Periodic use: 3 times/year	-	-	5.5%	12.5%	1.4% (3)
Periodic use: Medical prescription (surgery, amputation, after hospitalization)	1.8	-	3.6%	1.8%	1.4% (3)
Periodic: To monitor pregnancy	3.6%	7.3%	20.0%	-	10.9% (24)

* Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

In general, the informants perceived that NI-MI-GMD would assist patients to better follow-up and control their diabetes. Many informants mentioned the potential usefulness of the NI-MI-GMD to measure, register and track glucose levels, and use the aggregated information to verify if their glucose levels are under control and whether their dietary and exercise choices are leading to the desired therapeutic effect. Many informants perceived that functionalities to assist them in checking if they stay within normal glycaemic ranges would also be helpful.

Having more thorough access to and understanding of their measurements, in real-time and in a diachronic way, was perceived as helpful to anticipate hypoglycaemia or hyperglycaemia, or to act upon these events as early as they are detected by the NI-MI-GMD. Others considered that the information generated and processed by the NI-MI-GMD would be beneficial for them to take measurements-informed decisions on the administration of insulin or on the food or exercise that they may need. Aligned with this intended use of NI-MI-GMD, a few informants suggested that NI-MI-GMD could incorporate functionalities to help them have a quality lifestyle, such as daily reminders to take measurements or to look at their current and past measurements, or regular advices on dietary, exercise, or therapeutics.

In addition to using NI-MI-GMD to have information to better understand how their diabetes is being controlled, many informants also voiced out that they would use them to practise sport, to travel, or to engage in other social and leisure activities in which they perceived the use of conventional glucose meters is not much convenient. Others, especially HCW and caregivers, emphasised that NI-MI-GMD were more effective than glucose meters for caregivers to be able to conciliate their work and parental responsibilities. Be it with the aim to conciliate diabetes monitoring with parenthood or with leisure time, NI-MI-GMD would have, allegedly, a reassuring feeling that any unexpected or unwanted increase or decrease of glucose levels could be promptly detected.

A few suggestions were made regarding how NI-MI-GMD could be used not in a continuous way but in very specific situations such as: during pregnancy to ensure the mother and baby are healthy, after a hospitalisation related to diabetes to follow-up if glucose levels are stabilised (e.g., for a 15-day period), or before medical interventions (e.g., surgery, amputation...).

Finally, there were a few informants who suggested that NI-MI-GMD could integrate functionalities other than measuring and processing glucose levels. Suggestions included: to monitor heart rate or blood pressure, to measure cholesterol, and to test for pregnancy. The informants who made these suggestions were familiar with smartphones applications that can be used to measure different bodily parameters. Informants in the PLWD2 group were among the informants who more frequently expressed that they would appreciate all-in-one NI-MI-GMD that supported monitoring of comorbidities.

3.2.2. Target population: users and operators.

The majority of informants across all groups expressed how helpful NI-MI-GMD would be for children or for PLWD1 (Table 8). Some PLWD2 and HCW were of the opinion that NI-MI-GMD would be helpful for diabetics not on insulin regimens. Overall, only a few appreciated the potential utility of NI-MI-GMD for pregnant women.

In all countries, HCW, PLWD1, PLWD2, and caregivers and adolescents perceived that children could benefit from NI-MI-GMD. It was considered that children could benefit from NI-MI-GMD because their caregivers would be able to feel better if their children do not have to prick their fingers, and if they feel that they can keep track of their glucose levels even when they are at work or at home and their children are somewhere else.

*My son before was very playful with the ball. Well, because he got sick, he doesn't play with the ball much anymore [...]
Sometimes, I tell him, his little eyes dance like he wants to go play ball but as he sees he doesn't have the same ability as before, sometimes like a little like he's abstaining, right? [...]
I have seen that this patch [FreeStyle®] would mature him because he says "I am not a child like I was before". I mean, it would make him behave a little more... he's going to say "no, I no longer depend on my mom being behind me, on what I'm going to do, I'm not going to use my mother..."*
(Peru, Mother of a 11-years old male child who lives with type 1 diabetes)

Children were perceived by a few informants, especially in Kyrgyzstan and in Tanzania, not only as users but also as potential operators with sufficient agency to utilize the NI-MI-GMD autonomously. With a few exceptions, most caregivers and HCW explained how children are educated in diabetes monitoring since the very first moment they are diagnosed. Part of the early education includes the use of conventional glucose meters, and the calculation of insulin doses to adjust glucose levels depending on their measurements. Caregivers' perception was that, in addition to monitoring, there could be ancillary psychosocial benefits, since they and their children could feel safe when they are at school, sleeping at night, practising sport, or attending camps or other social activities.

Some HCW and PLWD1 were unsure about how useful NI-MI-GMD could be for PLWD2. However, most PLWD2 self-identified as potential users of NI-MI-GMD. Especially, the older informants in Kyrgyzstan and in Peru, were convinced that they could benefit from NI-MI-GMD in complement to any dietary and exercise efforts to reduce the chance of developing long-term complications, including the appearance of obesity, or of some of the renal, sight, and cardiovascular problems that elderly PLWD2 may be prone, in their perspective, to suffer.

Only a few informants indicated that other persons, such as individuals without diabetes or "diabetes educators" could be considered target users or NI-MI-GMD.

Table 8 - Target population, users and operators

Findings from the SSI, CI, FGDs:*					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Adults Type 1	72.7%	36.4%	63.6%	8.8%	45.2% (100)
Adults Type 2	50.9%	49.1%	72.7%	5.4%	44.3% (98)
Pregnant women [#]	1.8%	38.2%	52.7%	32.1%	31.2% (69)
Children (as users)	62.7%	69.1%	56.4%	50.0%	60.6% (134)
Children (as operators)	18.2%	3.6%	9.1%	17.9%	12.2% (27)
Parents (as operators)	34.4%	20.0%	41.8%	33.9%	32.6% (72)
Educators	-	-	5.5%	-	1.4% (3)
Without diabetes	-	7.3%	1.8%	-	2.3% (5)

* Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

[#] In general, informants did not specify if they were referring to women who developed gestational diabetes during their pregnancy, or to women with diabetes who became pregnant.

3.2.3. Infrastructure level

During the PAR sessions, the groups were requested to discuss what type of basic infrastructure (e.g., shelter, water, electricity, Internet connection) should be necessary for the use of NI-MI-GMD. Of the 29 PAR groups, a total of nine groups (none in Mali) chose infrastructure level as one of the 10 groups of characteristics that they would like developers of NI-MI-GMD to focus on (Table 9).

In the opinion of these groups, NI-MI-GMD for frequent or for sporadic use, as a minimum, must be able to operate in environments where there is access to electricity, water or to the internet. *Full Autonomy of Operation* was an optimal requirement (i.e., the “*ideal requisite*”, as many informants’ and interviewers’ interpreted what an optimal requirement means in a TPP for NI-MI-GMD) that was added to the set of cards of requirements for *Infrastructure Level* by a group of PLWD1 in Kyrgyzstan. To this group of PLWD1, NI-MI-GMD should operate even in places where there is absence of electricity, water or Internet connection.

There must be 2 types of devices. A high-level one for Lima, and an easier one for people from the provinces. Because in the provinces there are no computers [...] There you need a simple device: you put the strip in it, it gives an indicator, and it has a memory. For Lima, you can download [measurements] in the computer, and you can see them up for one month, the measurements...

(Peru, Male living with type 2 diabetes, 65 years old)

Table 9 - Requirements proposed for characteristic Infrastructure Level

Findings from the PAR:*		
	Type of use:	
	For frequent use [#]	For sporadic use [#]
Optimal requirements	Access to Internet (5) Access to water (1) Access to electricity (4) Full autonomy of operation (1)	Access to Internet (4) Access to water (1) Access to electricity (5) Full autonomy of operation (1)
Minimal requirements	Access to Internet (3) Access to water (3) Access to electricity (4)	Access to Internet (3) Access to water (2) Access to electricity (4) Full autonomy of operation (1)

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.3 Device.

3.3.1. Physical area of measurement.

The majority of informants expressed preference to measure their glucose levels on their arm, wrist or hand (Table 6). These were areas which, in some of the informants' opinions, individuals could just easily apply the device without others noticing, or wear the device comfortably and forget about having to remove it or to change supplies.

For children I would like this device to be on hand in the form of bracelet, otherwise she would lose it. Lock of the bracelet must be too sturdy (laughs). Some children, for instance don't wear earrings. To lose a hat for a child is 2 minutes. Therefore the device must be on the area within her sight, and fastened strongly.

(Kyrgyzstan, Mother of a 7-years old female child who lives with type 1 diabetes)

Interestingly, in all countries, there were discrepancies between what HCW suggested would be the ideal measurement areas and what PLWD1, PLWD2, adolescents, and caregivers suggested. Many HCW, concerned about the risk of stigma for their patients, were reluctant to recommend areas where diabetics could not use NI-MI-GMD covertly. Informants from the other study groups, on the other hand, did not express as frequently as HCW their concerns about stigma. In discussing best physical areas for measurement, many PLWD1, PLWD2 and caregivers expressed that that they would be more concerned about spoiling, harming, misplacing, or forgetting the NI-MI-GMD. To avoid these risks, visible and comfortable areas such as the abdomen, the hands, or the ears were also considered appropriate.

The interviewers used visual aids to let the informants know some of the NI-MI-GMD proposed for development by manufacturers⁵. After being exposed to these aids, some informants also added acceptance for the eyes, the fingers, the ears, or the mouth as areas for measurement. Although it was understood that NI-MI-GMD could not produce continuous measurements without the intervention of an operator in these areas, many informants expressed that what they would precisely want is a NI-MI-GMD that is portable, and that takes measurements only when they need them. In that scenario, the eyes, mouth, ears, fingers would be acceptable. The toes, the ankle, the shoulder, the armpit and other bodily areas were suggested by isolated cases.

Many informants opposed the eyes due to the discomfort they thought that inserting either a device or a testing strip would imply. A few male informants, most notably in Kyrgyzstan and Mali, considered that the ears would not be acceptable for Kyrgyz men as in their environment *"only women use earrings"*. In Kyrgyzstan, some female informants explained that they would not like the ear as, due to cold weather, it was common for them to wear winter scarves, hats, coats and other garments which could make glucose measurements difficult. Furthermore, some HCWs and PLWD1 disregarded the mouth because, in their opinion, if there are remnants of food in the oral cavity or in the teeth, the glucose measurements might not be reliable.

Twenty-one PAR groups chose *Physical Area of Measurement* as one of the 10 groups of characteristics that they would like NI-MI-GMD to focus on (Table 6). This characteristic was chosen by all groups in Mali and in Tanzania. In the groups' opinion, as a minimum, users of NI-MI-GMD for frequent or for sporadic use must be able to place them in their arms, wrists or hands. As an optimal requirement, NI-MI-GMD for frequent use should work when placed in the legs, abdomen and the earlobes. Earlobes could also be an area where NI-MI-GMD should work when used in a sporadic manner. As a minimal requirement, NI-MI-GMD should work when placed in the abdomen, legs, eyes or torso. The torso was also suggested as a place where, optimally, NI-MI-GMD for sporadic use should be able to take measurements.

⁵ See footnote 4.

Table 6 - Requirements proposed for characteristic Physical Area of Measurement

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Abdomen	12.7%	9.1%	12.7%	10.7%	11.3% (25)
Arm	32.7%	72.7%	36.4%	32.1%	43.4% (96)
Armpit	-	1.8%	-	3.6%	1.4% (3)
Back	-	12.7%	1.8%	3.6%	4.5% (10)
Brain	-	1.8%	-	-	0.5% (1)
Breast / Chest	-	-	5.5%	7.1%	3.2% (7)
Ear	7.3%	5.5%	32.7%	7.1%	13.1% (29)
Eyes	-	3.6%	20.0%	7.1%	7.7% (17)
Finger	7.3%	25.5%	30.1%	19.6%	20.8% (46)
Legs / Thighs / Ankle	3.6%	5.5%	16.4%	8.9%	8.6% (19)
Mouth / Tongue	1.8%	9.1%	32.7%	25.0%	17.2% (38)
Neck	-	-	3.6%	8.9%	3.2% (7)
Shoulder	1.8%	-	3.6%	12.5%	4.5% (10)
Toes	-	3.6%	-	1.8%	1.4% (3)
Wrist / Hand	62.3%	61.8%	76.4%	75.0%	70.1% (155)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Abdomen (1) Arm (4) Wrist / Hand (13) Legs (1) Earlobe (2)		Arm (6) Wrist / Hand (9) Torso (1) Earlobe (3)		
Minimal requirements	Abdomen (4) Arm (8) Wrist / Hand (6) Legs (2) Eye (1) Torso (1)		Abdomen (1) Arm (9) Wrist / Hand (5) Legs (3) Eye (2) Earlobe (3)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.3.2. Application and attachment to the body.

Opinions varied regarding the most acceptable shape of NI-MI-GMD. To the majority, devices ought to be comfortable to wear, easy to operate, and painless (Table 7). Based on these parameters, devices in the form of minimally-invasive sensors would be preferable to wearable devices in the forms of bracelets or watches. Common reasons associated with preference for minimally-invasive sensors were related to perceptions about these being more “*accurate*” (i.e., have less “*error margin*” as described by some informants in Kyrgyzstan) by informants who had used them or were knowledgeable of others who had used them (e.g., the FreeStyle Libre®).

Others, however, expressed a preference in wearable devices over minimally-invasive sensors. The informants who expressed preference for non-invasive devices in the forms of bracelets or watches were informants who practised sports or swimming and/or who had preferences for “*stylish*”, “*fashionable*”, and comfortable garments. A minority of them, especially in Kyrgyzstan, had read about an “*i-watch*” that was hypothetically going to be released soon to the market.

Table 7 - Requirements proposed for characteristic Application and Attachment to the Body

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Attached with anything adhesive	25.5%	20.0%	32.7%	25.0%	25.8% (57)
Attached with a band, belt, bracelet, cloth	78.2%	67.3%	72.7%	76.8%	73.8% (163)
Like an ear clip or earring	7.3%	7.3%	20.0%	1.8%	9.0% (20)
Like a necklace or bangles	-	-	1.8%	5.4%	1.8% (4)
Like contact lenses for the eyes	-	1.8%	3.6%	-	1.4% (3)
Like a strip that is placed in the tongue or eyes	1.8%	12.7%	20.0%	3.6%	9.5% (21)
Like a hearing device or earphones	-	-	1.8%	-	0.5% (1)
Like a thermometer for the armpit	-	1.8%	-	-	0.5% (1)
Like a pulse oximeter for the finger or the ear	12.7%	16.4%	32.7%	5.4%	16.7% (37)
Like a ring for fingers and toes	-	3.6%	-	5.4%	2.3% (5)
Like an anklet	-	-	1.8%	-	0.5% (1)
Like a chip that is introduced in the bloodstream	3.6%	-	-	-	0.9% (2)
Like a chip that is implanted under the skin	10.9%	12.7%	23.6%	10.7%	14.5% (32)
Like a watch wrapped around the wrist	56.4%	58.2%	67.3%	62.5%	61.1% (135)
Like a sensor applied with a micro-needle	-	12.7%	16.4%	-	7.2% (16)
Must be small, flat, easy to wear and hide	5.5%	3.6%	23.6%	19.6%	13.1% (29)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Band or clip (6) Adhesive (3) Temporary (only for measurement) (3)		Band or clip (5) Temporary (only for measurement) (6)		
Minimal requirements	Band or clip (2) Attached with an adhesive (5) Temporary (only for measurement) (4)		Band or clip (3) Attached with an adhesive (4) Temporary (only for measurement) (4)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

Other informants gave further ideas on how they would like to apply and attach the devices on the body, regarding minimally-invasive devices, sensors or devices similar to the FreeStyle Libre® (which was mentioned in Peru, and Kyrgyzstan). The majority of informants with previous experience of minimally-invasive sensors did not consider that applying them via a small needle was something to redesign. Nevertheless, a few female informants explained that placing the FreeStyle Libre® was uncomfortable or painful.

Commonly, there were complaints of how unstable on the body minimally-invasive sensors were due to the “adhesives”. A few informants thought of these adhesives as leading to allergic reactions or itchiness. Others thought of them as useless since the devices would fall off when showering, bathing or sweating. Especially in Kyrgyzstan, a country with multiple lakes, and where going to the sauna and swimming pool

Well, the inconvenience that it can have, well, it can break at any time... You know, in Mali here, when you walk and you see children fighting, you can stand between them to separate them, so that they stop... Yes, like for example if I see my little brother fighting, I have to stop to separate them. Well, when you separate them, if the hand of one of them hits this watch and breaks its screen, that will be a problem for you.

(Mali, Male living with type 1 diabetes, 23 years old)

was, allegedly, a common activity amongst the Kyrgyz informants. In this context, many informants stated that different ways to attach sensors (or, to remove them from the body, where necessary) were necessary.

A few informants mentioned “implants”. In a few instances, the informants – mostly female informants, familiar with contraception methods – referred to actual implantable devices. For others, it was unclear if they were actual minimally-invasive sensor users and maybe they considered sensors as implanted rather than as applied via a micro-needle to the skin – even if it was for a 15-30 days period only.

With regards to non-invasive devices, a few informants mentioned that, ideally, these should have some wristband, cuff, or cloth to attach them to the body, especially if they were to be worn on the hand or wrist.

Eleven PAR groups chose *Application and Attachment to the Body* as one of the groups of characteristics that they would like NI-MI-GMD developers to give priority to (Table 7). According to their choices, bands or clips should be always considered as a viable option to attach NI-MI-GMD to the body for frequent or sporadic use. NI-MI-GMD that are applied, but not attached, to the body in a temporary manner just to obtain a measurement, should also be designed both for frequent and for temporary use. In the groups’ opinion, the use of adhesives to attach NI-MI-GMD to the body must be seen as a minimal requirement for NI-MI-GMD for sporadic use, and as a minimal and optimal requirement for NI-MI-GMD for frequent use.

3.3.3. Degree of invasiveness

The majority of informants partaking in the interviewing encounters expressed preference for non-invasive over minimally-invasive glucose monitoring devices (Table 8). In general, it was commonly expressed that the majority of diabetics would prefer non-invasive devices that are harm-free. However, many informants stated that they could accept both non- and minimally-invasive devices: what would matter the most for some of them would not be the degree of invasiveness but other factors such as price and reliability of the results.

Among the ones who expressed preference for minimally-invasive devices, a few indicated that they could accept sensors that needed to be applied with a microneedle to measure glucose in the interstitial fluid (e.g., as in the Medtronic™ glucose sensor or in the FreeStyle Libre®, which were mentioned by many informants).

A minority of informants expressed that minimally-invasive would be preferable over non-invasive NI-MI-GMD for pregnant women. In Peru and Tanzania, participants expressed that these devices should be applicable to diabetic users of all kinds, including pregnant women.

Isolated voices suggested that, as minimally-invasive devices, they would accept the possibility of having a tattoo that measures glucose and sends the readings to a device; a measuring chip that is inserted in the bloodstream; or glucose measuring contact lenses.

Among the informants who expressed that they would want to use non-invasive devices, some expressed that they would prefer to have access to portable devices that they could have in their pockets or in their bags and just place over the skin (e.g., held with a band temporarily, or just applied for the measurement) the moment they would want to take a measurement. As non-invasive devices, two isolated voices suggested *laser jab* and *ultraviolet rays* to measure glucose levels without the need to intervene in the users’ skin.

Twenty-one PAR groups chose *Degree of Invasiveness* as one of the groups of characteristics that they would like NI-MI-GMD developers to concentrate on (Table 8). To the majority of these groups, optimally, NI-MI-GMD for frequent and sporadic use should be non-invasive. Only a few groups considered that optimal NI-MI-GMD could pierce the skin for application.

Table 8 - Requirements proposed for characteristic Degree of invasiveness

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Minimally-invasive: Microneedle to measure in interstitial fluid	1.8%	12.8%	21.8%	1.8%	10.9% (24)
Minimally-invasive: Others (chip, tattoo, contact lenses...)	-	1.8%	9.1%	1.8%	3.2% (7)
Non-invasive: Unspecified (Only, or preferably)	36.4%	58.2%	54.6%	12.5%	40.3% (89)
Non-invasive: Laser jab	-	1.8%	1.8%	-	0.9% (2)
Non-invasive: For all persons but for pregnant women	18.2%	3.6%	-	.	5.4% (12)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Can pierce the skin for application (2) Non-invasive (18)		Can pierce the skin for application (3) Non-invasive (17)		
Minimal requirements	Can pierce the skin for application (9) No trauma (no piercing of skin) (1) Non-invasive (9) Minimally-invasive (1)		Can pierce the skin for application (11) No trauma (no piercing of skin) (2) Non-invasive (6) Minimally-invasive (1)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

As minimal requirements, about half of the groups considered that NI-MI-GMD could pierce the skin for application. Less than half of the groups suggested that NI-MI-GMD for frequent or sporadic use ought to be non- or minimally-invasive, or be designed in a way that no trauma by piercing of skin could be caused to the user.

3.3.4. Sample type.

There were scarce narratives on the specimens preferred for taking measurements using NI-MI-GMD (Table 9). Only on specific occasions, informants expressed preference for measurements on interstitial fluid since these were perceived as closer to actual glucose levels in the blood. Usually, these were informants who expressed that they would rely more on capillary blood and glucose meters and that they would switch from glucose meters to NI-MI-GMD only if these were affordable, reliable, and had extra functionalities.

In opposition to what the PAR groups expressed, only a minority of informants in the SSI, CI and FGD discussed their preference for devices that could do optical measurements. Nevertheless, it must be noted that lack of expression of interest in 'optical reading' per se during the

interviewing encounters does not equate with lack of interest in NI-MI-GMD that would employ optical measurement techniques, as there were informants who expressed that they would like a NI-MI-GMD that that they could attach to their fingers or earlobes, and which could measure glucose levels "as a pulse oximeter".

With people who are bedridden, people in a coma for example, it's very difficult to get the saliva from these people. It's very, very difficult because you'll often find that their teeth are crooked, but yet you need saliva from the mouth, so it won't be easy to get it. But if it's the case of a fingerprint, even if the person is in a coma, you can take their hand and put it on the device, and it will give you the normal result.

(Mali, Female living with type 2 diabetes, 42 years old)

The voices of many informants in relation to their preferences for sample type were affected by the visual aids exposed to them by the interviewers⁶. After learning about some of the NI-MI-GMD under development at the time of study design (e.g., the NovioSense[™] non-invasive tear glucose sensor, or the glucoWISE[®]), there were informants expressing that they would find NI-MI-GMD that required eye fluids, saliva, or sweat to be acceptable.

Albeit none of the visual aids exposed by the interviewers include a urine-based NI-MI-GMD, there were informants in all countries – most notably, in Tanzania – who knew of urine strips used in clinics to measure glucose and other parameters. Thus, urine was also proposed as an acceptable sample type for glucose monitoring in all countries.

Twenty-two PAR groups chose *Sample Type* as one of their 10 priority characteristics for the development of NI-MI-GMD (Table 13). The PAR groups felt that, optimally, no specimen was needed as a requirement for frequent and sporadic users of NI-MI-GMD. Saliva was chosen by some PAR groups as a minimal and optimal requirement for both frequent and sporadic use of NI-MI-GMD. A few groups suggested sweat or tears as a minimum requirement of NI-MI-GMD for frequent or sporadic use. Urine was not an option in the set of cards presented to the participants. Perhaps due to the absence of urine glucose devices in the visual cards, no PAR chose urine as a sample type.

Table 9 - Requirements proposed for characteristic *Sample Type*

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Eye fluids	-	-	12.7%	8.9%	5.4% (12)
Interstitial fluids	1.8%	-	14.6%	-	4.1% (9)
No specimens (optical reading)	-	7.3%	16.4%	1.8%	6.3% (14)
Saliva	9.1%	21.8%	41.8%	23.2%	24.0% (53)
Sweat	3.6%	1.8%	3.6%	7.1%	4.1% (9)
Urine	3.6%	5.5%	1.8%	21.4%	8.1% (18)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	No sample needed (optical measurement) (12) Interstitial fluid (4) Saliva (7)		No sample needed (optical measurement) (11) Interstitial fluid (2) Saliva (8)		
Minimal requirements	No sample needed (optical measurement) (2) Interstitial fluid (3) Sweat (6) Saliva (10)		No sample needed (optical measurement) (3) Interstitial fluid (4) Sweat (4) Saliva (12) Tears (1)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

⁶ See footnote 4.

3.3.5. Measurement cycle.

Many informants described that, due to the expenditure associated with the use of glucose meters, lancets, and strips, they were not measuring their glucose very frequently (Table 14). Just a few informants who received consumables for free from the government or from NGOs, a few caregivers, and a few informants who expressed that they could finance their own strips, indicated that they were doing measurements as recommended by their diabetes care providers. Others, especially PLWD2, opined that they did not need to measure every day if stable with their medication. If NI-MI-GMD were available and users could use them affordably, most informants expressed willingness to measure more frequently.

A few informants said that, to encourage frequent or ongoing measurements, the NI-MI-GMD must be portable, and that measurements needed be taken when activated by the operator; be this operator the diabetic person or their caregiver. In almost half of the encounters, the informants suggested that they would measure every 6-12 hours. Others would use them as per need during the day but would like them to take measurements throughout the night. A few informants expressed that the device should have the option to let them programme themselves the frequency of measurements – rather than conforming to what the manufacturer indicated.

Interviewer: How often will you use [the NI-MI-GMDs]?

Informant: I [will] test twice in a day. I use like... for example, I use the time when I have not taken food and maybe in the evening when I have eaten food, I want to go to sleep, I check my sugar, isn't it? So that if I sleep, I estimate if I go till morning it won't disturb me or if it drops or anything that's how it will be"

(Tanzania, Male living with type 1 diabetes, 26 years old)

Table 10 - Requirements proposed for characteristic Measurement Cycle

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Only when activated by operator	7.3%	25.5%	18.2%	5.4%	14.0% (31)
Every 1-59 minutes	12.7%	1.8%	3.6%	1.8%	5.0 (11)
Every 1-2 hours	16.4%	3.6%	1.8%	1.8%	5.9% (13)
Every 3-4 hours	12.7%	3.6%	18.2%	10.7%	11.3% (25)
Every 6-12 hours	34.6%	29.1%	34.6%	60.7%	39.8% (88)
Every 2-3 days	1.8%	5.5%	14.6%	1.8%	5.9% (13)
Ongoing	23.6%	16.4%	14.6%	19.6%	18.6% (41)
Throughout the night	3.6%	-	1.8%	3.6%	2.3% (5)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Continuous (every few minutes) (12) Intermittent, requiring an intervention to get a reading (3) Intermittent, programmable in the device (8)		Continuous (every few minutes) (4) Intermittent, requiring an intervention to get a reading (5) Intermittent, programmable in the device (13) Every 6 hours with the help of someone (1)		
Minimal requirements	Continuous (every few minutes) (4) Intermittent, requiring an intervention to get a reading (5) Intermittent, programmable in the device (14)		Continuous (every few minutes) (3) Intermittent, requiring an intervention to get a reading (9) Intermittent, programmable in the device (11)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

Twenty-two PAR groups chose *Measurement Cycle* as one of the group of characteristics for NI-MI-GMD developers to focus on (Table 14). In an optimal scenario, for sporadic use, one group in Peru suggested that NI-MI-GMD should allow measurements every six hours. For frequent use, half of the groups thought NI-MI-GMD should be able, optimally, to take measurements every few minutes. For sporadic use, half of the groups thought that NI-MI-GMD should be programmable to allow for intermittent measurements. As minimal requirements, half of the groups also agreed that this requirement should be available. The option to require an intervention to get a reading was proposed as a minimal and optimal requirement for both frequent and sporadic use.

3.3.6. Additional equipment required.

The informants did not explore specifically during the IDI, CI or FGD what type of consumables or equipment would be necessary, in addition to the NI-MI-GMD, to assist users to perform measurements or to reading them. Nevertheless, during the data collection encounters, a commonly shared view was that the NI-MI-GMD itself should be sufficient and that no consumables (e.g., strips, swabs) had to be necessary. The majority of informants thought that the less items needed the better, and some explained how uncomfortable it is to carry lancets, strips, cotton and glucose meters to take measurements. A few, with experience of FreeStyle Libre®, reflected on how uncomfortable it is to carry the reader as well as the mobile phone. There were just a few isolated voices suggesting that NI-MI-GMD should come with additional equipment such as, “a cord” to transfer the data to a computer, a memory card, or that, if the NI-MI-GMD had test strips, that these needed to be reusable.

Fourteen PAR groups chose *Additional equipment required (any once-off or regular extras)* as one of the group of characteristics for NI-MI-GMD developers to focus on (Table 11). For half of these groups, access to a mobile phone would be necessary to operate NI-MI-GMD in any of the scenarios discussed. More than half of the groups were of the opinion that no additional equipment should be necessary, and that the measurements should be read on the device itself (i.e., assuming that the device includes both the sensor and reader).

Table 11 - Requirements proposed for characteristic Additional Equipment

Findings from the PAR:*		
	Type of use:	
	For frequent use [#]	For sporadic use [#]
Optimal requirements	Mobile phone (5) None (reading on device) (9)	Mobile phone (4) Reader (1) None (reading on device) (8)
Minimal requirements	Mobile phone (6) Reader (3) None (reading on device) (7)	Mobile phone (5) Reader (5) None (reading on device) (6)

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.3.7. Duration of use.

During the interviewing encounters, there was a paucity of insights on expected duration of NI-MI-GMD when unopened (Table 12). When opened, in countries such as Tanzania, the informants did not express any preferences regarding how long the devices should last.

There were just a few informants reflecting on how long the NI-MI-GMD could be expected to last. Their opinions were regarding the expected cost of the NI-MI-GMD, and ranged from as

little as one month to 10 years or more. Hence, the findings regarding duration of use to inform the requirements for this TPP characteristic should be taken with caution. Reasons for their opinions were not homogeneous: whilst a few wished the device lasted many years due to the difficulty to get a prescription to buy a NI-MI-GMD abroad and to import it to the country, others wished that they lasted longer due to their high cost.

If these are comfortable devices, and if these devices are used not once or twice every 3 days but, will be changed once a month, or last up to a year, then the cost will not play a big role. But if it requires a lot of supplies, then the cost will matter for any patient, especially if there are several children in the family, not necessarily with diabetes. Or if it's a lonely person who does not have additional sources of funding.

(Kyrgyzstan, 49 years old female endocrinologist partaking in an FGD)

In all countries, there were informants expressing that they wanted NI-MI-GMD to be waterproof and resistant to extreme weathers and impact, so that they could last longer, especially when worn by children who are daily exposed to harm and loss in the school's playground or by people who practise water sports.

Regarding the duration of the sensors for devices that are minimally-invasive, it is worth to note that, among the informants

with experience with FreeStyle Libre®, some explained that they wished that the sensors could be on the body longer than one month – due to their elevated cost. Some informants in Kyrgyzstan and in Peru, with experience with FreeStyle Libre®, explained that they exchange tips with other users via WhatsApp® on how to make them last a full month (even if the manufacturer only recommends users to wear them for 15 days).

Table 12 - Requirements proposed for characteristic Duration of Use

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
1 month	9.1%	-	9.1%	-	4.5% (10)
2-3 months	5.5%	1.8%	-	-	1.8% (4)
1-2 years	5.5%	-	3.6%	-	2.3% (5)
3-4 years	5.5%	-	1.8%	1.8%	2.3% (5)
5-9 years	5.5%	-	-	-	1.4% (3)
>10 years	7.3%	-	1.8%	-	2.3% (5)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	4 weeks (frequency to exchange patch) (2) 3 months (frequency to exchange patch) (1) 6 months (frequency to exchange patch) (2) 1 year or longer (in case of non-invasive hardware) (18)		4 weeks (frequency to exchange patch) (2) 3 months (frequency to exchange patch) (2) 1 year or longer (in case of non-invasive hardware) (18) 5 year or longer (in case of non-invasive hardware) (1)		
Minimal requirements	4 weeks (frequency to exchange patch) (2) 3 months (frequency to exchange patch) (16) 6 months (frequency to exchange patch) (1) 1 year or longer (in case of non-invasive hardware) (4)		4 weeks (frequency to exchange patch) (2) 3 months (frequency to exchange patch) (15) 1 year or longer (in case of non-invasive hardware) (4)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

Twenty-two PAR groups chose *Duration of Use* as one of characteristics that they would like NI-MI-GMD developers to concentrate on (Table 12). To the majority of groups, as a minimum, NI-MI-GMD for frequent and sporadic use should last three months. It was unclear if they referred to the device itself or to the frequency the supplies (e.g., the sensors) had to be replaced. To the majority, optimally, NI-MI-GMD without any non-invasive hardware for frequent and sporadic use should last one year, or longer. One group suggested that, ideally, NI-MI-GMD without any non-invasive hardware for sporadic use should last at least five years.

3.3.8. Interchangeability.

Narratives on interchangeability were very scarce. A few isolated voices suggested that NI-MI-GMD, if portable and non-invasive, could be used in hospital or clinic environments, by different users. An informant mentioned that, for instance, NI-MI-GMD could be shared among pregnant women when they are in a maternity clinic or labour ward.

It was also suggested that, within the household, portable non-invasive devices could be shared between the diabetic persons and other non-diabetic relatives with interest in knowing their glucose levels. Or, between more than one person living with diabetes in the same household. In this regard, a physician from Mali emphasised that NI-MI-GMD should not be interchangeable as it will complicate clinical decision-taking since it will be difficult for diabetes care providers to know – by looking at the devices' records – to which person in that household the measurements corresponded to.

3.4. Utility.

3.4.1. Data display.

In most countries, the majority of informants expressed preference for having access to the glucose measurements either in the NI-MI-GMD themselves or in their own mobile phones (Table 17). Only in Kyrgyzstan, where many informants had knowledge of FreeStyle Libre®, half of the informants expressed that they would not mind using a reader, in addition to the sensor or to the phone, to read their measurements. However, a common narrative across all study settings was that the less equipment (in reference to readers) the better for diabetics in their contexts).

My [girl] children don't have a phone. When she's married, I'll buy her a phone. That's what I usually do. I buy a phone to the one [girl] who finds a husband. Otherwise at home, my daughters don't have the right to a phone. Every house has these rules, and today the telephone is spoiling many children. When you give them a phone, they don't do anything anymore.

(Mali, Father of a 17-years old female adolescent partaking in a CI)

There were informants, among the ones who expressed preference for seeing their measurements in their mobile phones, who specified that they would like to download applications from Apple Store® or Google Play® that could be installed in their smartphones. These applications, as per their narratives, would not serve only to see their last glucose measurements, but also to see the measurements of the past weeks, and to verify if they stayed within normal ranges, among other functionalities.

It must be noted that there were also voices in all countries who thought that mobile phones would complicate monitoring of glucose levels, as they – and, in their opinion, other diabetics as well – could run out of batteries, see their mobile phones stolen or lost or broken, or could simply have problems to procure and own a smartphone. There were informants who, via their narratives, reminded that women in some households and regions lack the same opportunities to access smartphones than men have.

Twenty-two PAR groups selected *Data Display* as one of the top 10 characteristics that developers should consider in their development of NI-MI-GMD (Table 17). Aggregated

findings from the choices made by these groups indicate that, as a minimum but also optimally, NI-MI-GMD for frequent and sporadic use should display the measurements on the mobile phone, the device itself, or in another device (e.g., a computer, other family members' devices). The readers were the less popular option, as they were only chosen frequently as an optimal requirement for NI-MI-GMD for sporadic use.

Table 13 – Requirements proposed for characteristic Data Display

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
On a computer	5.5%	7.3%	20.0%	1.8%	8.6% (19)
On a conventional glucose metre	1.8%	-	-	-	0.5% (1)
On a smartphone app (iPhone and Android)	30.9%	18.2%	38.2%	1.8%	22.2% (49)
On a mobile phone	72.7%	58.2%	81.8%	64.3%	69.2% (153)
On other devices (e.g., lamp, Alexa, Miao Miao...)	-	1.8%	3.6%	-	1.4% (3)
On a reader	52.7%	1.8%	14.6%	10.7%	19.9% (44)
On the same NI-MI-GMD	27.3%	70.9%	65.5%	82.1%	61.5% (136)
On a smartwatch	3.6%	5.5%	5.6%	1.8%	4.1% (9)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	On phone (10) On specific reader (2) On another device, computer, database, other family members (2) On device (9)		On phone (8) On specific reader (5) On another device, computer, database, other family members (1) On device (9)		
Minimal requirements	On phone (8) On specific reader (1) On another device, computer, database, other family members (4) On device (9)		On phone (6) On specific reader (2) On another device, computer, database, other family members (3) On device (11)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.4.2. Connectivity device to reader or other equipment.

The informants in the SSI, CI or FGD did not provide many insights on the requirements that NI-MI-GMD could meet to facilitate the transmission of measurements data from the devices to other equipment (e.g., mobile phones, websites, mobile apps). A few isolated voices mentioned that NI-MI-GMD should be Bluetooth-enabled, or have “*infrared systems*” to transfer data. One informant specified that they would not like data transfer to be dependent on “*Near Field Communication, because not all smartphones have it*”. Despite lack of suggestions on requirements for this TPP characteristic, as discussed below in subheading 3.4.3, a majority of informants agreed to the possibility of using NI-MI-GMD with the function to share their measurements data with relatives, partners or healthcare professionals. In Mali, there were isolated cases who expressed concern of the possibility of “hackers” having access to the shared data and manipulating them.

Nineteen PAR groups chose *Connectivity* as one of their top 10 characteristics (Table 18). Only one HCW group from Mali chose *Connectivity*. As optimal requirements for NI-MI-GMD for

frequent and sporadic use, the majority of groups were of the opinion that NI-MI-GMD should be equipped with wireless data transfer to any third-party data management software. For frequent use, the capacity to wireless data transfer to device-specific data management software was considered by a majority as both a minimal and optimal requirement. Half of the groups thought that, as a minimum, devices for sporadic use would not need connectivity to transfer data to any software if they display the measurements on the device itself. With the exception of the informants who thought that it was not necessary to transfer data if these were displayed in the device, most of the requirements discussed during the PAR were not mentioned during the SSI, CI or FGD.

Like now a hacker, you know, this kind of people are many in Mali here, they target only one person, so I don't like this person, this person is weaker than me so they will go against you. Imagine they have your phone hacked or they have your stuff hacked [...] so if they have the internet connection, they hack it your information will be sent, that will stay in their hands [...] They mean you harm. If you are at 0.56, they can send 4.56 so automatically the gentleman [the doctor] calls you to tell you to increase the insulin when he found that you were all the way down so you increase the insulin it can cause complications.

(Mali, Male living with type 1 diabetes, 28 years old)

Table 14 - Requirements proposed for characteristic Connectivity

Findings from the PAR:*		
	Type of use:	
	For frequent use [#]	For sporadic use [#]
Optimal requirements	Wireless data transfer to device-specific data management software (7) Wireless data transfer to any third-party data management software (8) Not needed if data is displayed on device (3) Transfer to healthcare worker and store in the cloud (1)	Wireless data transfer to device-specific data management software (4) Wireless data transfer to any third-party DM software (12) Wireless data transfer to healthcare worker (1) Not needed if data is displayed on device (2)
Minimal requirements	Wireless data transfer to device-specific data management software (11) Wireless data transfer to any third-party data management software (1) Wireless data transfer to healthcare worker (2) Not needed if data is displayed on device (3) Transfer to a healthcare worker (2)	Wireless data transfer to device-specific data management software (6) Wireless data transfer to any third-party data management software (3) Not needed if data is displayed on device (9) Transfer to a healthcare worker (1)

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.4.3. Data management.

Majority of informants were of the opinion that NI-MI-GMD should have enough internal memory to store several weeks of measurements data; the capacity to transform these data into tables or graphs or ranges that could help users visualize how they are “succeeding” in controlling their diabetes and “staying within normal ranges”; and the functionality to transmit these data to relatives, friends or healthcare providers with whom the users would intend to share their measurements (Table 19).

I guess, if for example that device that I will be wearing could be able to record [measurements] and deliver them to the hospital, or to be recording itself on the internet... So, for example the doctor wants to take a look, will just access that connection and see my results and others' results.

(Tanzania, 15-years old female adolescent living with type 1 diabetes, and partaking in a CI)

Table 15 - Requirements proposed for characteristic Data management

Findings from the SSI, CI, FGDs:*					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Measurements need to be archived / stored	83.6%	78.2%	78.2%	85.7%	81.4% (180)
Measurements need be organized in a glucose diary that is downloadable in pdf / printable	1.8%	5.5%	23.6%	7.1%	9.5% (21)
Measurements need be converted into ranges, graphs, averages, tables	81.8%	5.5%	50.9%	71.4%	52.5% (116)
Measurements need be traceable by means of allowing the users to run queries in the system	-	9.1%	1.8%	7.1%	4.5% (10)
Measurements could be shared with close persons (relatives, doctors...) other than the NI-MI-GMD user	83.6%	50.9%	72.7%	89.3%	74.25 (164)
Measurements should be uploaded and processed in a specific web-based information system	12.7%	10.9%	9.1%	3.6%	9.0% (20)
Measurements could be stored, processed and displayed in social media / messaging applications	-	1.8%	1.8%	-	0.9% (2)
Measurements should not be modifiable once stored	-	-	1.8%	-	0.5% (1)
Measurements should be sent to a “global diabetes monitoring system”	-	-	-	1.8%	0.5% (1)
Measurements should be processed in the language of choice of the user	-	1.8%	-	-	0.5% (1)
Measurements should be shared with the public/private health insurance	-	-	1.8%	-	0.5% (1)
Measurements should be processed with a time and geo stamp	-	-	1.8%	-	0.5% (1)

* Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

Other functionalities were suggested by a minority of informants. Suggestions included that NI-MI-GMD should allow users to upload their measurements in social media, or to share them via social messaging; that NI-MI-GMD should impede users to modify the measurements once these are registered in the device’s back-end; that measurements data should be “*uploaded to a global diabetes monitoring system*” or to public and private health insurance records; and that measurements should be processed in vernacular languages or in any language of choice of the users.

Well, as I have said, if I don’t have the device, I have to travel to the health centre. Above all things, this country knows insecurity, do you see? It might be that bandits can say that you have anything of value, and that they attack you even if you have nothing with you [...] Well, with this device, the data [measurements] are being sent to the doctor, and he will answer you through messaging to advice you on the products [medicines] to get. I believe that is its advantage.

(Mali, Female living with type 2 diabetes, 61 years old)

3.4.4. Power source.

Few narratives were expressed on what source of power or electricity NI-MI-GMD may need to operate effectively (Table 20). On a few occasions, there were mentions of the possibility of charging the NI-MI-GMD with batteries, with solar power means, or via a USB cable to a computer or source of power.

Rather than speaking about how to power the NI-MI-GMD, some informants preferred to emphasize how important it would be for their environments to consider the need to reduce

users' dependency on access to power sources. This could be especially relevant for NI-MI-GMD that are connected to readers or to mobile phones, and that depend on these phones to be fully charged to allow users to see their readings and have access to them whenever they would need to.

Fourteen PAR groups chose *Power source* as one of their top 10 characteristics (Table 20). Of these, six and four were from Tanzania and Mali, respectively.

According to the choices made by these 14 groups, an optimal requirement for NI-MI-GMD for sporadic and frequent use would be that all pieces of equipment should be rechargeable. As a minimum, NI-MI-GMD for sporadic and frequent use should be able to operate with single-use batteries. One PAR group from Peru expressed that, optimally, NI-MI-GMD should be rechargeable with human body-emitted heat (lit., '*calor humano*' in Spanish).

Informant: *The devices I told you have batteries. The batteries can run out. That's the one that reads the number, so if it uses a charging system, it will be better and it will show you that the charge has run out, so you can charge it.*

Interviewer: *They should have the charger system, not a battery.*

Informant: *It should not use battery. Or, it may be those that use solar energy, but it should give the readings.*

(Tanzania, Female living with type 2 diabetes, 44 years old).

Table 20 - Requirements proposed for characteristic Power source

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Long-lasting rechargeable batteries	3.6%	14.5%	12.7%	10.7%	10.4% (23)
No need for electricity or source of power	-	-	-	3.6%	0.9% (2)
Solar powered	-	-	3.6%	5,36%	2.3% (5)
Wireless charger	-	-	1.8%	-	0.5% (1)
No charger (can be lost, stolen)	-	-	3.6%	-	0.9% (2)
Charger better than batteries	3.6%	3.6%	5.5%	5.7%	4.5% (10)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	All pieces of equipment should be rechargeable (10) Single-use batteries (1) Rechargeable with solar energy (2) Body heat (1)		All pieces of equipment should be rechargeable (11) Single-use batteries (2) Rechargeable with solar energy (1)		
Minimal requirements	All pieces of equipment should be rechargeable (5) Single-use batteries (8) Rechargeable with solar energy (1)		All pieces of equipment should be rechargeable (6) Single-use batteries (7) Rechargeable with solar energy (1)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.4.5. Operating and storage temperature.

No narratives were found in relation to at what exact temperatures NI-MI-GMD should be stored or should be functioning (Table 21).

Indirectly, in Kyrgyzstan, some informants suggested that any NI-MI-GMD should work during “harsh winters”, and put emphasis on the need for devices to work under water or in humid environments such as saunas. But no specific data on humidity levels were given.

Informants in Tanzania and in Mali also addressed the need for temperature or humidity parameters, as some did mention the specific need of a device that can withstand extreme heat temperatures. This consideration would be, in their opinion, especially important for any end-user who may have to work outdoors.

And of course, it must be waterproof. If for our country, then we have Lake Issyk-Kul, where everyone goes in the summer, where the water is generally salty. Baths and pools are also popular with us, that is, a person still faces a humid environment, so the device should be waterproof, if possible
Kyrgyzstan, Male living with type 1 diabetes, 24 years old).

Eleven of the 29 PAR groups chose *Temperature* as one of their top 10 priorities for the development of NI-MI-GMD (Table 16). For frequent and sporadic use, as a minimum and in optimal conditions, NI-MI-GMD should be able to operate in environments with <0° - 45° C temperatures and 10-90% relative humidity. Optimally, irrespective of the frequency of use, NI-MI-GMD should, according to PAR groups in Mali, operate in temperatures >30° C. The requirement *can work in all conditions*, was chosen as a minimum requirement for NI-MI-GMD for sporadic and frequent use only by a group of PLWD2 in Tanzania.

Table 16 – Requirements proposed for characteristic Temperature

Findings from the PAR:*		
	Type of use:	
	For frequent use [#]	For sporadic use [#]
Optimal requirements	<0°C – 45°C, 10-90% relative humidity (6) 5-35° C, 10-70% relative humidity (3) 30° C or above (1) -35-65° C, 10-90% relative humidity (1) Optimization for the environment and operating temperatures in Kyrgyz Republic (1)	<0°C – 45°C, 10-90% relative humidity (6) 5-35° C, 10-70% relative humidity (3) 30° C or above (1) -35-65° C, 10-90% relative humidity (1) Optimization for the environment and operating temperatures in Kyrgyz Republic (1)
Minimal requirements	<0°C – 45°C, 10-90% relative humidity (5) 5-35° C, 10-70% relative humidity (1) -35-65° C, 10-90% relative humidity (1) Optimization for the environment and operating temperatures in Kyrgyz Republic (1) None Can work in all conditions (1)	<0°C – 45°C, 10-90% relative humidity (6) 5-35° C, 10-70% relative humidity (1) -35-65° C, 10-90% relative humidity (1) Optimization for the environment and operating temperatures in Kyrgyz Republic (1) Can work in all conditions (1)

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.4.6. Alerts.

Almost all informants were interested in having NI-MI-GMD that could alert them when their glucose levels either dropped or increased outside normal glycaemic ranges (Table 22). Although many informants suggested that alerts should be different for hypoglycaemia and for hyperglycaemia, there were no consensus on what the format of the alerts should be. There were myriad preferences, ranging from loud sounds to fine beeps or “tic tac” noises, to lights and

colours, or to vibrations. A few isolated voices suggested that the NI-MI-GMD could provide “an electric shock” to their user, or that they could “bring a cold sensation” to the users if it detected an emergency.

Most informants expressed what they would prefer based on their experiences with their own mobile phones. A few others, however, were concerned that if the alerts were too evident, they would even “disturb” other persons, unnecessarily “wake up all the family in the house”, or – for the ones who were most concerned about being discriminated against for their diabetes – disclose the users’ diabetes status to third persons unaware that they are living with the disease.

Table 17 – Requirements proposed for characteristic Alerts and Alarms

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Types					
Sound (strong, prolonged, loud, klaxon-like...)	50.9%	43.6%	54.5%	21.4%	42.5% (94)
Sound (tic-tic, beep, small, soft...)	10.9%	21.8%	12.7%	19.6%	16.3% (36)
Voice warning the user about the situation	10.9%	5.5%	7.3%	1.8%	6.3% (14)
Vibration	12.7%	14.5%	14.5%	16.1%	14.5% (32)
Colours, flashes, blinks, flickers	3.6%	18.2%	12.7%	16.1%	12.7% (28)
Gives the user an electric shock	-	-	-	3.6%	0.9% (2)
Brings coldness to the user	-	-	-	1.8%	0.5% (1)
The alarm will be different depending on the circumstance	3.6%	16.4%	25.4%	41.1%	21.7% (48)
Conditions					
The user can program the alarm	14.5%	3.6%	9.1%	1.8%	7.2% (16)
The alarm can be sent via SMS to contacts	7.3%	1.8%	1.8%	5.4%	4.1% (9)
The device does a video call to emergency contacts	3.6%	-	-	-	0.9% (2)
The device publishes the alarm in the users’ social media	-	-	3.6%	-	0.9% (2)
The device sends the alarm to the emergency room	-	-	3.6%	-	0.9% (2)
Circumstances					
When a hypoglycaemia	58.2%	61.8%	74.5%	57.1%	62.9% (139)
When a hyperglycaemia	60.0%	60.0%	61.8%	60.7%	60.6% (134)
When an increase in ketone bodies	1.8%	5.5%	1.8%	-	2.3% (5)
When the sensor needs be removed	-	-	-	3.6%	0.9% (2)
When nutritional recommendations are needed	7.3%	-	1.8%	1.8%	2.7% (6)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Hypoglycaemia and hyperglycaemia (2) Loss of connectivity (1) Night-time hypoglycaemia (6) Reading reminder (6) When outside of user-defined target range (14)		Hypoglycaemia and hyperglycaemia (1) Ketone check reminder (4) Loss of connectivity (2) Night-time hypoglycaemia (6) Reading reminder (7) When outside of user-defined target range (7)		
Minimal requirements	Hypoglycaemia and hyperglycaemia (3) Ketone check reminder (4) Loss of connectivity (3) Night-time hypoglycaemia (8) Reading reminder (5) When outside of user-defined target range (5)		Hypoglycaemia and hyperglycaemia (2) Ketone check reminder (11) Loss of connectivity (3) Night-time hypoglycaemia (2) Reading reminder (5) When outside of user-defined target range (4)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

^{*} Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

In some cases, informants also discussed who should be hearing or seeing the alerts. The majority thought that the alerts should be produced by the NI-MI-GMD themselves and targeting the user. A few also suggested that the devices should post the alerts in the users' social media profiles; send SMS or alert messages to the users' relatives; or, warn the "ambulance system" or "emergency room". Some caregivers explained that the alerts should be both in the children's NI-MI-GMD and in their parents' phones as children may not react to the alerts or, as a caregiver from Mali put it, they may "hide the alert status to their parents".

Finally, besides alerts for situations of hypoglycaemia or hyperglycaemia, it was suggested that NI-MI-GMD could also be programmed to have alerts when their users suffer an "increase in ketone bodies"; when users need reminders to take their medication or take glucose measurements around meals; or when users need nutritional advices. It was indicated that users themselves should be able to program the type, format, and frequency of the alerts in the devices themselves or in the devices' smartphone application.

Twenty-six PAR groups considered that NI-MI-GMD developers should consider as crucial the functionality of *Alerts and Alarms* (Table 17). Only one group of caregivers in Peru and the HCW groups in Tanzania did not give priority to this group of characteristics. In the groups' opinions, all NI-MI-GMD, be it for frequent or for sporadic use, should have alerts for night hypoglycaemia, alarms for hypoglycaemia and hyperglycaemia, reading reminders, and alerts when measurements fall outside of user-defined target ranges. Ketone check reminders were considered as a requirement in all scenarios, save as an optimal requirement for NI-MI-GMD for frequent use, and it was especially considered relevant as a minimal requirement for NI-MI-GMD for sporadic use.

3.5. Performance and results.

3.5.1. Measurement accuracy.

No informant in this study expressed if the measurements should be displayed in mg/dL or in mmol/L.

How the measurements should be displayed was an area that did not receive many ideas from the sample (Table 23). A few suggested that measurements should be accompanied by an automated voice that reads them aloud, which will be useful specially for the illiterate users (in Mali) or for PLWD2 that are aged and with visibility problems.

Other informants, probably influenced either by the visual aids provided by interviewers or by their exposure to devices such as glucose meters or other minimally-invasive monitoring devices, proposed that, to be able to anticipate problems and thus act upon, measurements in

I would suggest that if the sugar has gone above the required range, there should be warnings that... maybe the red colour or what... just anything. But it alerts you that your sugar has risen. And also, if it drops like that, there should be something that shows that your sugar has dropped. [...] Even a child will also make it easier for the very young child.

(Tanzania, Female living with type 1 diabetes, 21 years old).

Informant: If you want to quickly kill a diabetic, he must give him a device that gives false results, so with that he will drown.

Interviewer: So, if you want to end a diabetic...

Informant: Here, you have to give him a device that gives him fake results, so you're going to mix up all his things. (Laugh).

Interviewer: If the device gives the real...

Informant: [...] For example, if you give me a device that does not tell the truth, it tells me that my blood sugar is falling while the blood sugar is going up, so if I take something that raises the blood sugar [then] I am dead, right?

(Mali, Father of a 17-years old female child who lives with type 1 diabetes)

the NI-MI-GMD should be presented in different colours depending on their severity, and/or accompanied with “arrows”, “dolls”, or texts indicating if the users’ glucose levels are high, low, normal or if they are decreasing or increasing.

An informant from Kyrgyzstan indicated that the devices’ screens should have a backlight for users to be able to easily read their measurements at night time. Two informants mentioned that the time stamps needed to be displayed with the measurement, as this would be helpful for users who miss looking at the screen precisely when the measurement is done by the device.

Twenty-two PAR groups considered that NI-MI-GMD developers should consider as crucial the characteristic *Measurement Accuracy* (Table 23). To the majority of these groups, optimally, NI-MI-GMD for frequent and sporadic use should display the precise measurements. To the majority of groups, as a minimum, NI-MI-GMD for frequent and sporadic use should, as a minimum, display range indications. These narratives are aligned with some of the preferences expressed by IDI, CI and FGD informants who suggested that the exact measurements should be displayed in the NI-MI-GMD themselves and that, if users wanted more advanced data visualization, NI-MI-GMD could be programmed in a way that measurements could be transformed into ranges, graphs, or tables.

Table 18 - Requirements proposed for characteristic Measurement accuracy

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
...accompanied by an automated voice that reads the measurement	-	1.8%	3.6%	3.3%	2.3% (5)
...in numbers	7.3%	20.0%	23.6%	10.7%	15.4% (34)
...using a colour system (esp. when increase/decrease)	-	7.3%	14.6%	23.2%	11.3% (25)
...with arrows pointing up/down	-	3.6%	10.9%	3.6%	4.5% (10)
...with a 'muñequito' (i.e., doll) indicating sugar levels	-	-	1.8%	-	0.5% (1)
...with an indication if levels are "down", "low" or "high"	-	-	-	3.6%	0.9% (2)
...with backlight (i.e., no need to turn on light for night readings)	1.8%	-	-	-	0.5% (1)
...with ranges, averages, means, graphics...	12.7%	7.3%	25.5%	8.9%	13.6% (30)
Findings from the PAR: [*]					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Precise number (17) Precise number & range indication (1) Range Indication Only (4)		Precise number (18) Within 90% precision (1) Range Indication Only (3)		
Minimal requirements	Precise number (10) Within 90% precision (1) Range Indication Only (11)		Precise number (9) Within 90% precision (1) Range Indication Only (12)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

^{*} Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.5.2. Calibration.

Irrespective of the fact that most participants might have been using conventional glucose meters – and, in some cases, minimally-invasive devices that may require calibration –, there were very few suggestions regarding how the informants would want newer NI-MI-GMD to be calibrated (Table 24).

It is not necessary to constantly use continuous monitoring devices. If you bought a Freestyle Libre sensor, this doesn't mean that you only need to use it all the time. That is, in principle, you can alternate with a glucose meter. Why I'm saying that you don't have to use the sensor only because it measures glucose in the intercellular fluid, that is, the readings are slightly delayed and there is a possibility of a change in the indicator. In order to get the most accurate value, you need to calibrate the sensor with a glucose meter.

(Kyrgyzstan, Female diabetes school educator, 49 years old)

On the other hand, there were multiple informants expressing that they would continue using glucose meters: not to calibrate, but to confirm if they could trust the measurements given by the NI-MI-GMD.

Isolated voices expressed that they would prefer a NI-MI-GMD that needs calibration once a week or in the earlier stages of NI-MI-GMD use.

Informants were asked if they would trust the NI-MI-GMD. Some patients and healthcare workers were of the opinion that they would trust the NI-MI-GMD measurements since they confided in scientists, health ministries and regulatory authorities to examine and prove the

devices are trustworthy before allowing the general public to access them. In this regard, however, there were informants in Kyrgyzstan explaining that many people imported NI-MI-GMD from abroad and when this happened it was more difficult to assess their reliability. However, in countries such as Peru and Tanzania, a few informants expressed total trust in NI-MI-GMD by the very fact that they were available for purchase.

Some informants expressed that they would trust NI-MI-GMD as far as they knew that they “could have a higher error range than glucose meters”, but they would still use NI-MI-GMD to monitor their trends and obtain records rather than to be aware of potential complications such as hypoglycaemia or hyperglycaemia. Some of these informants, in spite of their concerns on “error range”, expressed how they would carry out glucose meters at the start or periodically to check how different measurements were between the glucose meter and the NI-MI-GMDs. This was expressed as a way to find trust in the device, especially in initial usage and over prolonged use.

The need for assurance through NI-MI-GMD-provided measurements that were aligned with glucose meters-provided measurements was expressed by most informants, irrespective of their knowledge of or experience with NI-MI-GMD. Intuitively, it was explained how they would use glucose meters to certify if the NI-MI-GMD-provided measurements were correct or, at least, not too misleading. In Kyrgyzstan, a few physicians and endocrinologists added that they would take venous blood to compare results with those produced by the NI-MI-GMD. This narrative was not found among PLWD1, PLWD2, or caregivers.

Twenty-two PAR groups chose *Calibration* as one of the 10 groups of characteristics that they would prioritise in the development of NI-MI-GMD (Table 19). Of the 22 groups, only one was from Tanzania. These groups did not propose many requirements for each of the four scenarios under discussion. In general, in their opinion, optimally, NI-MI-GMD should need no calibration. As a minimal requirement, most groups also proposed that NI-MI-GMD required minimal calibration with SMBG. This perception is aligned with some of the concerns expressed by the informants partaking in the SSI, CI and FGD.

Table 19 - Requirements proposed for characteristic Calibration

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Calibration with SMBG	3.6%	5.5%	16.4%	1.8%	6.8% (15)
Comparison with laboratory analyses (e.g., A1C) just to trust	7.3%	-	7.3%	-	3.6% (8)
Comparison with measurements from glucose meters to trust	30.9%	-	30.9%	14.3%	19.0% (42)
No user calibration needed	1.8%	-	1.8%	-	0.9% (2)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Minimal user calibration with SMBG (once in a while) (3) No user calibration needed (6) Compulsory periodic calibration by a specialist (1)		Minimal user calibration with SMBG (once in a while) (4) No user calibration needed (6)		
Minimal requirements	Minimal user calibration with SMBG (once in a while) (5) No user calibration needed (2) Minimum calibration only (not specified how) (1) Compulsory periodic calibration by a specialist (1) Minimum calibration by specialists (occasionally) (1)		Minimal user calibration with SMBG (once in a while) (6) No user calibration needed (1) Minimum calibration only (not specified how) (2) Minimum calibration by specialists (occasionally) (1)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

3.6. Purchasing considerations.

3.6.1. Price.

There was no consensus about how much informants would be willing to pay for the NI-MI-GMD at first, or on how much they would be willing to pay per month for supplies and support systems (Table 25). Notably, willingness to pay more than 100.00 USD was higher in Kyrgyzstan than in any other country.

These data need to be interpreted with caution as the question on how much one would pay for a NI-MI-GMD, or for its supplies or support system, was not posed homogeneously across the study countries. It is also important to note that not all informants suggested a maximum amount they would be willing to pay for a NI-MI-GMD.

However, overwhelmingly, informants in all countries insisted on how, nowadays, even the glucose meters and the supplies needed (i.e., lancets, cotton swabs, strips) for conventional glucose monitoring are perceived as expensive in many households. Many informants disclosed that they were “middle class” or that they had economic means to ponder whether they could make a decision regarding the purchase of a NI-MI-GMD, and many expressed being aware that many other persons living with diabetes in their countries were not in that advantaged position.

Interviewer: Ok, and if health authorities do not provide glucose monitoring devices, what can be done to the glucose monitoring devices so that people can buy them?

Informant: It should be available in hospitals at affordable prices... so that every patient who comes with diabetes, are told on the importance of having of having their own machine for self-monitoring at home, and it is available at the hospital at an affordable price. For example, if a machine is sold for 50 thousand and a hospital one can get it for 25,000, people can buy it.

(Tanzania, Female physician, 50 years old)

Table 20 - Range of prices proposed by the sample, by country

Findings from the SSI, CI, FGDs:*					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Less than 5.00 USD	-	7.3%	3.6%	16.1%	6.8% (15)
Between 5.01-10.00 USD	-	3.6%	-	25.0%	7.2% (16)
Between 10.01-30.00 USD	18.2%	12.7%	12.7%	33.9%	19.5% (43)
Between 30.01-50.00 USD	14.5%	16.4%	-	17.9%	12.2% (27)
Between 50.01-100.00 USD	-	5.5%	14.5%	-	5.0% (11)
More than 100 USD	52.7%	9.1%	29.1%	-	22.6% (50)

* Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

3.6.2. Business model.

Not many proposals in reference to how PLWD1 or PLWD2 could have access to NI-MI-GMD were expressed (Table 21). A minority of informants with experience with NI-MI-GMD suggested that the current option of paying for the device and then paying every 2-4 weeks for its supplies (e.g., sensors) and the maintenance of its software and technical support, was acceptable for them. In general, there was a majority of informants suggesting that the NI-MI-GMD should be either fully, or partially, subsidised by the countries' health authorities – or, provided for free by non-governmental agencies and other charities – so that the financially vulnerable households could have access to, and benefit from, NI-MI-GMD.

Table 21 - Requirements proposed for characteristic Purchasing Characteristics

Findings from the SSI, CI, FGDs: ^A					
	Countries:				Total Encounters (n= 221)
	Kyrgyzstan (n=55)	Mali (n=55)	Peru (n=55)	Tanzania (n=56)	
Annual payment	1.8%	5.5%	5.5%	7.1%	5.0% (11)
Device free of charge, and subsequent payment for supplies	-	-	1.8%	5.4%	1.8% (4)
Modular payment depending on devices' add-on features	-	-	1.8%	1.8%	0.9% (2)
Monthly payment	3.6%	16.4%	12.7%	21.4%	13.6% (30)
Once-off payment for the device, and supplies at a reduced cost	3.6%	-	3.6%	3.6%	2.7% (6)
Once-off payment for the device only (No supplies needed)	16.4%	-	10.9%	7.1%	8.6% (19)
Payment of the device in various instalments	-	3.6%	1.8%	-	1.4% (3)
Findings from the PAR:*					
	Type of use:				
	For frequent use [#]		For sporadic use [#]		
Optimal requirements	Same as my current monitoring costs (3) Less than my current monitoring costs (20) Prepared to pay more than if device helps improve my daily management (5) Through public or private insurance, free of charge (1)		Same as my current monitoring costs (5) Less than my current monitoring costs (18) Prepared to pay more than if device helps improve my daily management (3) Through public or private insurance, free of charge (1)		
Minimal requirements	Same as my current monitoring costs (15) Less than my current monitoring costs (6) Prepared to pay more than if device helps improve my daily management (6)		Same as my current monitoring costs (15) Less than my current monitoring costs (9) Prepared to pay more than if device helps improve my daily management (4)		

^A Data highlighted in **bold green** correspond to isolated voices (i.e., only 1 informant per country).

* Data highlighted in **bold blue** correspond to the most popular requirements per discussed scenario.

[#] In () the total number of PAR groups that selected each requirement.

A few informants also elaborated on the possibility of NI-MI-GMD being delivered to diabetic patients in the same way as glucose meters in some healthcare facilities, whereby healthcare providers would provide the NI-MI-GMD free of charge (or, at a very reduced cost), and patients would continue paying for the supplies and support systems needed to operate the NI-MI-GMD. Nevertheless, there were informants who recognized that glucose meters are distributed at no cost in some facilities to the patients because where companies make revenue is out of selling fungible and supplies.

The majority of informants expressed preference to incur in a first and single payment for a NI-MI-GMD, and not have to incur in subsequent expenditure. If once-off costs to obtain the NI-MI-GMD were high, some informants expressed preference for purchasing it via monthly or annual instalments.

Irrespective of how much informants expressed that they would be willing to invest in a NI-MI-GMD, it must be noted that there were informants in all countries concerned with the freedom that the local vendors have, allegedly, to increase the prices of medical devices and make them unaffordable for the most deprived patients. In Mali and in Kyrgyzstan there were informants who directly suggested that the governments should pass regulations to set a price ceiling or price caps for future NI-MI-GMD.

It would be good if our government would provide the devices via a public-private partnership. For example, the government provides the device, and a patient pays a third or half of the device price. There is no meaning to give device totally free. If the patient pays half of the device cost, and then spends a definite amount of money on supplies every month, he or she will use this device more accurately. He will be motivated to control his glucose levels and to achieve compensation.

(Kyrgyzstan, Female paediatric endocrinologist, 57 years old)

The characteristic *Purchasing Characteristics* was chosen by all PAR groups (Table 21), with the exception of one PAR group of HCW in Kyrgyzstan and of one PAR group of PLWD2 in Tanzania, as an aspect that NI-MI-GMD developers should prioritise. Albeit informants in the SSI, CI and FGD had put emphasis on the need to distribute NI-MI-GMD free of charge through public or private health insurance, only one PAR group considered that the distribution of NI-MI-GMD free of charge could be considered as an optimal requirement to be reflected in the TPP for NI-MI-GMD. To the majority of PAR groups, as a minimum, NI-MI-GMD should cost the same as their current glucose monitoring devices, and, optimally, they should cost less.

4. STRENGTHS AND LIMITATIONS

This is a mixed-methods study that applied an IRB-approved harmonised protocol in 4 different LMIC. The protocol's data collection procedures were administered consistently in all study sites, which allows for comparability of informants' preferences and expectations of NI-MI-GMD.

In this study, country teams used a mix of purposive and snowball sampling techniques. Access to a variety of informants was ensured, albeit representation of female informants was higher than representation of male informants in some of the study groups. Recruitment strategies in each country were successful in engaging a diverse sample that included both NI-MI-GMD-naïve and -experienced persons. Participation of diabetes care providers and diabetics with exposure to NI-MI-GMD allows for a comparison of their expectations of NI-MI-GMD with those of individuals who have only been exposed to conventional glucose meters.

This is a study that pursued trustworthiness. Triangulation of findings was possible via the incorporation of different data collection techniques, analytical tools, and analysts: there were encounters conducted face-to-face and online; there were encounters with individuals, couples, and groups; there were encounters where interviewing techniques were used and where PAR-informed exercises were used; in addition to the LSS, country analysts were involved in the

processing, coding, and analysis of the informants' voices throughout the data collection stage; and an in-depth immersing in the informants' narratives was conducted alongside the preparation of personal reflexive memos by the LSS.

Immersing into the informants' narratives was not a task without its challenges. Many informants aimed at exploring in-depth with the interviewers how NI-MI-GMD could be developed to better help them see their needs met in their contexts. A few informants were hesitant, however, to give opinions on what type of improved functions and technical features they could appreciate in future NI-MI-GMD. In Kyrgyzstan and in Peru, where the informants had more knowledge of some of the NI-MI-GMD available in the market, the narratives around the requirements of interest for a TPP for NI-MI-GMD were more detailed than in Mali or Tanzania. However, Mali and Tanzania have both more fragile health systems than Kyrgyzstan and Peru. In consequence, narratives from informants from Mali or from Tanzania around the access and care barriers that people living with diabetes – or, in general, with non-communicable chronic diseases – in these countries face were very much insightful, and will merit further grounded analyses.

Reluctant, or timid, attitudes to build a narrative around the type of NI-MI-GMD that the informants would want to use in a future was addressed in different manners by the interviewers. In all countries, there was a large team of recruiters, interviewers, translators, transcribers and group moderators who exchanged challenges with data collection on a routine basis, and who assisted each other with solutions to improve the quality of data collection throughout all field work stages. All these study collaborators received training by the LSS in recruitment techniques, informed consent processes, and culturally-sensitive data collection. Unfortunately, since all the countries conducted the study at the same time, it was not feasible for the LSS and study sponsors to carry out exhaustive quality control and iterative data collection, transcript review, and participatory analysis. The inability to carry out data collection and analysis iteratively affected some of the encounters with the informants which were conducted by the interviewers with less skills to probe NI-MI-GMD-naïve informants for more detailed and elaborated insights of interest for the TPP for NI-MI-GMD for LMIC.

Knowledge was identified as a motivator that fuelled discussion around the minimal or optimal requirements that NI-MI-GMD for LMIC could have. Across all countries, knowledge of and past experience with NI-MI-GMD was more frequently reported by PLWD1 and caregivers than by informants from the other study groups. A few physicians and nurses working in diabetes care – most notably, in Kyrgyzstan – had some knowledge of the NI-MI-GMDs available in the market. However, most HCW in this study reported that they lacked knowledge of NI-MI-GMD. This aspect affected HCWs' contributions to the discussions around the TPP for NI-MI-GMD. As this is qualitative research, we cannot generalize and affirm that HCW engaged in diabetes care in LMIC are not capacitated to recommend NI-MI-GMD to their patients, or to support the ones who have taken the decision to use an NI-MI-GMD. However, since having a NI-MI-GMD-literate trained healthcare workforce in LMIC is crucial to help improve diabetics' and caregivers' glucose monitoring capacities, we can recommend that further quantitative research on HCWs' attitudes towards NI-MI-GMD are conducted in LMIC.

The risk of social desirability is inherent to most qualitative research methodologies. In this study, social desirability might have affected the way some informants volunteered to discuss the requirements of a technological solution that they had never used or even seen or heard about before their engagement in the study. Social desirability might have affected the way some of the informants with limited access to diabetic care resources emphasized how much useful they thought the usage of future NI-MI-GMD could be for them. Although therapeutic misconception was not a bias we anticipated, the possibility that some informants could expect better access to diabetes control means via their participation in the study should not be disregarded.

Based on the informants' narratives, seemingly, many adult persons living with diabetes and caregivers of children living with diabetes use smartphones, have social media profiles, participate in group social messaging, and are willing to learn about technological innovations to improve their diabetes care. Nevertheless, their constraints to access the health system to receive quality care, their dependence on non-profit organization, their risk of facing discrimination for their status as diabetics, or their very access and utilisation of glucose meters vary from person to person. Beyond shared commonalities such as interest in technology and fluency with smartphone applications, sociocultural, political, and family environments in Mali and Tanzania affect the preferences for NI-MI-GMD in a different way than in Kyrgyzstan and Peru. In this regard, this study has merely presented the results of a multi-country content analysis process: further analysis from a socio-epidemiological perspective that consider country-by-country analyses might throw more light onto how resource-deprived populations would access, use and benefit from NI-MI-GMD designed with the purpose of being affordable, safe and useful for LMIC.

Finally, it must be noted that an observer bias might also have been introduced by some of the interviewers. Due to difficulties in probing some informants, some interviewers made leading questions and remarks during some data collection encounters, which might have affected some of the informants' expressed insights regarding what type of NI-MI-GMD they would find acceptable. As a result of the interactions between some informants and some interviewers, there were preferences that were expressed multiple times across all study groups in all countries (e.g., preferences for optical glucose sensors that look like watches). Considering the possibility of observer bias, we recommend taking into equal consideration the frequent voices, the not-that-frequent voices, and all the isolated opinions.

5. CONCLUSION

NI-MI-GMD for LMIC need be designed in full consideration of the needs of persons who might have socio-economic-, clinical-, gender-, and/or health system access-related impediments to fully utilize and benefit from the features and functions that NI-MI-GMD designed for high-income countries have. The impediments vary from geography to geography. There is no homogeneity regarding barriers to utilization of NI-MI-GMD in LMIC. However, extreme weather conditions, lack of financial means, stock-outs of essential medical and diagnostic supplies, or insufficient qualified healthcare workforce are among the challenges that most people living with diabetes in LMIC may routinely face.

In the light of the findings of this qualitative research, ideally, NI-MI-GMD should be able to operate in settings where access to the Internet, water or electricity are not guaranteed. To overcome lack of access to the Internet, NI-MI-GMD could be plug-and-play without the need to have network connection, display the measurements in the devices themselves, and be either Bluetooth-enabled or have a USB/C-type (or similar) connection to allow transfer of measurements data to other devices (e.g., a mobile, a laptop).

In settings where access to clean water (or to means to make water clean) is not guaranteed, NI-MI-GMD would not require any contact of the device with any mucosa (e.g., the eye, the mouth), or the introduction of a microneedle to measure glucose levels in the interstitial fluid. Optical glucose sensors which would not require any fungible or additional utensils, would be preferable. In environments where there is not ongoing power supply, NI-MI-GMD should be easily rechargeable by means of using solar-powered batteries. NI-MI-GMD that cannot be solar-powered could better use chargers (the same that people use to charge their phones) rather than rechargeable batteries.

NI-MI-GMD for LMIC could be small, easy-to-apply devices that diabetic and non-diabetic persons could utilize either in a sporadic way just by placing them, or approaching them, to their body, or in an ongoing way by attaching them using any hypoallergenic adhesive or a band or cuff, to any bodily part of their choice.

The possibility of using a NI-MI-GMD with the capacity to take accurate glucose measurements in any part of their bodies would be important, especially, for diabetics who are concerned about discrimination; for those who practice any work, sport or leisure activity that might jeopardise the integrity of the NI-MI-GMD; or, for parents who fear that they might be easily lost, stolen, broken, or damaged. The ability to change the NI-MI-GMD from one part of the body to another based on the users' preferences, can be perceived as helpful to navigate some of the inconveniences of using a NI-MI-GMD that requires a permanent fixation in a specific part of the body.

NI-MI-GMD for LMIC must be waterproof, impact resistant, and designed to operate in extreme winter and summer temperatures. They could need no calibration. They could have programmable alarms for hypoglycaemia and hyperglycemia. The NI-MI-GMD could help the users choose the format of the alerts (e.g., strong sound, vibration, flashes...) they would like to program. The NI-MI-GMD could also have the option to program alerts to users when glucose measurements are needed; when they need to self-administer insulin; or when they have an appointment with their diabetes care providers. Users could also indicate the devices if they would want the alarms or reminders to be audible in their devices, in their smartphones or push-button phones, or in other relatives' or caregivers' phones.

Having NI-MI-GMD with the function to automatically share, in real-time, the users' glucose measurements with other persons would be especially important for caregivers of children and elders. In addition to the function of sending glucose measurements to other devices or to persons other than the NI-MI-GMD users, the NI-MI-GMD must have the capacity to store all glucose measurements in its internal memory (or, in an app- or cloud-based database linked to the NI-MI-GMD); to transform measurements into glucose diaries with a format similar to the diaries diabetics use to maintain in their contexts; to inter-operate with web-based electronic diabetic patients records to allow telemonitoring of the users by diabetes care providers; or to publish selected units of data (e.g., a very low glucose level) in the users' social media or social messaging of choice.

Users of NI-MI-GMD need also have the possibility of programming the NI-MI-GMD so that they can read and interpret their measurements depending on their preferences. Visually-impaired users could choose if they would want to hear the devices reading aloud the measurements or see the measurements displayed in larger font sizes. Children and low-literate individuals could learn to interpret the severity of their measurements if these were displayed using different colours, or emoticons, or arrows, or similar culturally-congruent symbols, and if these were accompanied by sounds, blinks, or flashes.

NI-MI-GMD as stand-alone devices could be developed with the option to see their functions enhanced by allowing their users to update them via a free of charge application that they could install in their phones and in their trusted persons' phones. These applications should be considered a complement of the devices. Diabetics in LMIC should not be forced to have a smartphone to be able to use a NI-MI-GMD. The functioning of NI-MI-GMD should not depend on users' access to wi-fi, or to 4G/5G networks. In addition to storing, interpreting, and transmitting measurements data, these applications could also provide nutritional and lifestyle advice and medication and appointment reminders to users, or they could help users monitor other vital signs and health-related parameters (e.g., heart rate, blood ketones).

Finally, future NI-MI-GMD should have a cost per year inferior to what users spend in a glucose meters and strips. They need to function without the need to procure any consumables. Persons living with diabetes and caregivers need to have access to a range of payment options, as some would prefer to pay a monthly subscription to use a NI-MI-GMD, and others would prefer to pay a quarterly or an annual subscription (i.e., provided the NI-MI-GMD are supported by an application or electronic system). Optimally, a single payment for a long-lasting device that works on its own should be made feasible to ensure users in LMIC consider the use of NI-MI-GMD an affordable solution to enhance their glucose levels monitoring.

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APPENDIX 1 – Interview Guide

The Interview Guide below was translated into Russian, French and Spanish and adapted, in each country, for the study target populations and for the type of encounters to be conducted (i.e., SSI, CI, FGD). Probes to further explore each theme were determined on a country-by-country basis.

THEME A – Diabetes

- How do you explain what diabetes is to people in your environment who lack knowledge of this condition?
- Can you tell me about your history with diabetes?
- Can you tell me about your history as a diabetes care provider?
- Who has given you education on diabetes management and control and how?
- Socially, how is diabetes –and people affected by it– perceived in this context?
- How is your daily management (incl. treatment) of people living with diabetes?
- How frequently do you monitor (or ask them to monitor) their glucose levels?
- What type of insulin regimes are available to them?
- What are the strategies to control diabetes that you recommend them?
- How frequently do you ask them to go to the clinic for a follow-up?

THEME B – Control of Diabetes

- In your case, what are your strategies to control your diabetes?
- What type of insulin regimes are you on? (i.e., What insulin are you using? How much do you pay for insulin(s) (pack size and pack price of each plus presentation (vial, pen or cartridge) and delivery devices (1 insulin syringe or 1 pen needle)?
- Total cost of insulin and delivery devices per month?
- How frequently do you monitor your glucose levels?
- What is your experience with self-monitoring your glucose levels?
- At what age, and how, you started being more autonomous in your control?
- How have you detected, monitored, and controlled hypoglycaemias?
- How have you detected, monitored, and controlled hyperglycaemias?
- What type of problems do you face when trying to control your diabetes?
- What are the root/structural causes of these problems, in your opinion?
- How do health institutions and healthcare providers address these problems?
- How should things be different?

THEME C - The Role of Technology

- How could technology assist to overcome problems for diabetes control?
- What is your opinion of glucose meters? What do they lack to be perfect?
- Which technological innovations do you know that could help people with diabetes control their diabetes?
- How could these innovations avoid the type of problems we discussed before?
- How could these innovations improve parental control on their children?

- How could technology innovations reduce diabetes-related stress and reduce disruption in day-to-day life?

THEME D - Glucose Monitoring Devices (GMD)

- Which glucose self-monitoring devices are you familiar with (besides glucose meters)?
[If no devices were mentioned during exploration of Theme C]
- Do you recommend them to your patients? Which one/s, exactly?
- Do you know people who use them? What for?
- Do you use them? What do you use them for?
- How much did you pay for each component (sensor, reader, transmitter etc)?
- How often do you have to replace each component?
- What does each component cost when replaced?
- Can you tell me who introduced them to you? And, what convinced you to use them?
- What are (or could be) the advantages of those devices for you?
- What are (or could be) the disadvantages of those devices for you?
- What type of people in your country could be interested in these devices?
- If these devices were easily available and affordable to all (e.g., provided by the health services), under what type of circumstances would people use them?
- If you don't use them: In what type of circumstances would you use them?
- If you use them: Are there any circumstances where you don't use them but you would like to?
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THEME E - Requirements

- Can you describe the ideal GMD for you in terms of user features?
- Where on the body would you like the GMD to measure (arm, wrist, torso, ear, eye)?
- If the GMD is attached to your body over a longer period of time, how would you like this to be (adhesive, wristband, clip, implanted, other)?
- In terms of frequency of measurement, how frequently would you use your GMD to measure your glucose levels?
- What types of alarms or warnings should GMD have to prevent hypoglycaemia/hyperglycaemia?
- How would you like to see the glucose reading that the GMD provides (e.g., on the device itself, via a reader/smartphone...)?
- What would you like to do with your own measurement data? (Manage in an app, enter into a log book...)
- With whom would you like to share your measurement data?
- How much would you trust the data coming from a new device?
- What should GMD have to help type 2 diabetes who do not need that regular monitoring of glucose?
- What should GMD have to help pregnant women with gestational diabetes?

THEME F – Societal, Clinical, and Technological factor

- Are there rumours in the community/diabetic people/clinics about GMD?
- How supportive will your health provider be if you decided to use GMD?
- How supportive will your family/partner be if you decided to use GMD?
- What would deter you from telling others that you use GMD?
- What would deter you from advising other people with diabetes to use GMD?
- What would deter you from advising patients with diabetes to use GMD?
- What would deter you from using GMD to decide on what is best for your child?

THEME G - Cost

- When you last obtained glucose meters? How much did you pay for each?
- When you last obtained lancets? How much did you pay for each?
- When you last obtained strips? How much did you pay for each?
- How much do people generally pay for 1 meter?
- How much do people generally pay for 1 lancet?
- How much do people generally pay for 1 test strip?
- If the health authorities do not provide GMD, what could make GMD appealing so that diabetic persons could buy them?
- What could make GMD appealing so that governments/health insurances buy them?
- How much would you/people be willing to pay for the ideal GMD?
- What price could you afford for a non-/minimally invasive glucose monitoring system (as an annual payment, per test or a monthly subscription)?

APPENDIX 2 – PAR Cards

PAR Cards of high-level categories or dimensions (including characteristics within this category). In the first part of the PAR session exercise, the informants, distributed in groups of 6-7 informants per table in the room, were asked to discuss each card separately, and to pile them up according to what would be in their opinion the dimensions that they would like NI-MI-GMD developers to prioritize.

DEVICE (Body) - Physical area of measurement - Attachment to the body - Degree of invasiveness - Sample type	DEVICE (Technical) - Additional equipment or consumables required - Duration of use - Measurement cycle - Calibration needs	UTILITY - Data display - Connectivity / data management - Alerts and user guidance - Power source - Operating temperature	PERFORMANCE and RESULTS Measurement accuracy of the device	PURCHASING CONSIDERATIONS - Price - Business model
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PAR Cards of characteristics. In the second part of the PAR session exercise, the informants were asked to discuss each card separately, to select their preferred 10 cards, and to pile up these 10 cards up according to what would be in their opinion the characteristics that they would like NI-MI-GMD developers to focus on.

DEVICE Physical area of measurement (Where on the body should be measured)	DEVICE Attachment to the body (If it stays, how should it be fixed in place?)	DEVICE Degree of invasiveness (To what extent should it damage any part of the body)	DEVICE Sample type (Interstitial fluid, sweat, saliva, no sample needed)
DEVICE Additional equipment required (Any once-off or regular extras)	DEVICE Duration of use before any hardware needs to be replaced (Number of measurements (or days of use) that can be done with device before ex-change is needed)	DEVICE Measurement cycle (How should measurement happen, intermittent or continuous)	DEVICE Calibration (Any need for user calibration)
UTILITY Data display (How to get the result)	UTILITY Connectivity/data management (For data storage, tracking, connecting to other devices)	UTILITY Alerts/user guidance	UTILITY Power source (Battery, rechargeable, etc...)
UTILITY Operating temperature (For all pieces of equipment)	PERFORMANCE Measurement accuracy (Reliability of the result)	PURCHASING CONSIDERATIONS Price and business model	SCOPE Infrastructure level (Access to electricity, internet, water)