Title:
Feasibility of using patient-reported outcome measures with visually impaired children/young people attending Paediatric Ophthalmology clinics.

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No conflicting relationship exists for any author.

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Contributorship statement:
JR and VT conceptualised and designed the study. AR designed the survey, prepared materials, recruited participants and collected all data. AR and MCB performed data analysis. The manuscript was written by AR, VT and JR, with MCB contributing to the final version.

**Online supplemental materials:**
The following should appear online only: Appendix, Supplementary data.

**Abbreviations/Acronyms:**
Patient-reported outcome measure (PROM)
Vision-related quality of life (VQoL)
Functional vision (FV)
Visual acuity of the logarithm of the minimum angle of resolution (logMAR)
Index of multiple deprivation (IMD)
United Kingdom (UK)
ABSTRACT

Objective: To explore feasibility of using child/young person patient-reported outcome measures (PROMs) routinely in practice, using vision-specific instruments and paediatric ophthalmology as the exemplar.

Methods: Participants comprised patients aged 8-17 years, with visual impairment or low vision (visual acuity of the logarithm of the minimum angle of resolution (logMAR) worse than 0.3 in the better eye), attending the Department of Ophthalmology at Great Ormond Street Hospital, London, UK. All participants completed age-appropriate PROMs before attending their outpatient appointment. Half were randomly assigned to completion at home, with the choice of paper-and-pencil or electronic format. The other half were invited to complete PROMs during their hospital appointment, and randomly assigned to completion format. All participants completed a face-to-face survey exploring their attitudes and preferences. Analysis comprised survival analysis, and direct comparisons of proportions, with complementary qualitative data analysis.

Results: 93 patients participated. 48 (98%) completing PROMs at home chose the paper-and-pencil format. Completion at home took longer than at hospital (median=20, versus 14 minutes, \( p < 0.001 \)). Visual acuity was associated with completion time (\( p = 0.007 \)) and missing data (\( p = 0.03 \)). Overall, 52 (60%) reported a preference for completion at home but there was no clear preference for format (37 (43%) preferred either format).

Conclusion: PROM completion at home ahead of hospital appointments may be preferable for collecting complete, high-quality datasets. Despite equipoise on preference for format, the majority of those completing at home chose the traditional
paper-and-pencil format, despite impaired sight. These findings should inform implementation of child/young person PROMs into routine practice.
Introduction

Patient-reported outcome measures (PROMs) afford children and young people the means by which to explain the daily impact of living with their condition and have their voices heard in clinical settings. Although mandatory routine use of PROMs in adult healthcare is longstanding, their equal value in children’s healthcare has been recognised more recently. Their routine use as adjuncts to clinical assessments may be particularly valuable for understanding disease progression or impact of treatment on chronic conditions during childhood and adolescence, as individuals grow up and encounter age- and disease-specific challenges.

Visual impairment (VI) is a prime example. However, there is a limited literature regarding the challenges and feasibility of using PROMs routinely in child healthcare. To date, the attitudes and preferences of patients with VI, or indeed, any chronic condition (i.e. the intended users) remain unexplored.

Psychometrically robust, child-appropriate PROMs are now available for use by children and young people aged 8 up to 18 years, which capture vision-related quality of life (VQoL) and functional vision (FV). The minimum age reflects the established literature about the challenges of capturing reliable and valid self-report from children younger than 8 years. As a model for children’s health care more broadly, we investigated feasibility of using these PROMs routinely in paediatric ophthalmology practice, alongside the preferences of children and young people.

METHODS

This study was approved by the National Health Service Research Ethics Committee for UCL Great Ormond Street Institute of Child Health and Great Ormond Street Hospital, London, UK (REC reference: 17/LO/1484) and followed the tenets of the
Declaration of Helsinki. Participants aged >16 years gave informed consent and those aged <16 years and their parents gave informed consent to participate.

Children and young people were eligible if they were i) visually impaired, severely visually impaired or blind (visual acuity in the better eye of logMAR 0.48 or worse, due to any visual disorder), but without any other significant impairment (i.e. learning, sensory or motor), or on the threshold of this criteria (visual acuity in the better eye of logMAR 0.3 or worse with a certification of VI, and additional visual defects, or fluctuating acuity); ii) aged 8-17 years; and iii) scheduled to attend a follow-up appointment at Great Ormond Street Hospital between October 2018 and April 2019.

Procedure

This study was designed to assess patient's preferences and indicators of feasibility relating to both ‘setting’ (i.e. PROM completion at home versus during the hospital visit) and, with electronic patient records starting to become widespread throughout the UK,11 ‘format’ (i.e. paper-and-pencil versus electronic methods).

Eligible patients were invited to complete PROMs aligned to their next hospital appointment. Using simple randomisation,12 participants were assigned to either ‘home’ or ‘hospital’ completion setting. Those assigned to ‘home’ had free choice of format, receiving both large-print paper-and-pencil versions and a web-link embedded in the invitation letter to a standalone online version. Those assigned to ‘hospital’ were randomly assigned to either paper-and-pencil or electronic format (presented on a tablet device) and completed the PROMs in the Ophthalmology clinic waiting area, as the ‘real-world’ setting for routine PROM use.

All participants self-reported difficulty to complete the PROMs using a 4-point Likert scale ranging from 1: Very easy to 4: Very difficult or impossible.
An open-ended questionnaire was verbally administered to elicit participants’ attitudes and preferences. Responses were manually recorded, and entered into NVivo 10.13

Invitation packs (described below) were sent to patients’ families 6 weeks before their upcoming hospital appointment, followed by a phone call 1-2 weeks later and the day before the appointment.

Materials

The PROMs administered were the Vision-related Quality Of Life (VQoL_CYP)5-7 and the Functional Vision (FVQ_CYP)8 9 instruments, our robust and validated instruments developed for, and with, the population of children/young people with VI in the UK. The two age-appropriate versions (for 8-12 and 13-17 year olds) of each instrument were used.7 9

The paper-and-pencil version comprised a booklet containing the PROMs and additional questions probing time taken, difficulty, and help needed to complete either PROM. The corresponding electronic format was developed using Qualtrics software.14 Both were tested for accessibility through consultations with a member of the clinical team who is visually impaired and has extensive expertise in adapting written material for children and young people with VI.

The study pack comprised age-appropriate invitation letters, information sheets and consent/assent forms. The booklet containing the two PROMs was included in invitation packs sent to those completing PROMs at home, so that participants could make an informed decision about participation. A pre-paid envelope was provided for the return of materials.
An open-ended questionnaire to elicit participants’ attitudes and preferences towards using PROMs was developed (see Appendix) and administered.

Analysis

Four indices of feasibility were measured: a) time to complete each PROM, b) quantity of missing data, c) self-reported completion difficulty and d) self-reported preferences. Quantitative analysis comprised descriptive statistics using R version 3.6.1. Pearson’s correlation coefficient, Chi-squared, Wilcoxon-Mann-Whitney (U) and Kruskal-Wallis (KW) tests were used as appropriate, assuming a significance level at 0.05. Pairwise comparisons were tested using a Bonferroni correction. Kaplan-Meier estimates were used to explore time spent completing PROMs. Differences in completion time were assessed using the log-rank test. We fitted multinomial logistic regression models using IMB SPSS Statistics 24 to compare odds of participating in the four conditions of location and format.

Qualitative data from the verbal questionnaire were organised thematically into descriptions of key issues.

We used the STROBE cross-sectional checklist when writing our report.

RESULTS

Ninety-three subjects participated (Figure 1).

The sociodemographic and clinical characteristics of the sample are shown in Table 1. Their mean age was 11 years (SD=2.4), 48 (52%) were male and 51 (55%) were White British. Forty-four (47%) were visually impaired and 10 (11%) were severely visually impaired or blind (WHO taxonomy). Thirty-nine (42%) had low vision with additional visual field restriction and/or fluctuating acuity.
Multinomial logistic regression models demonstrated no significant differences between the groups assigned to home versus hospital completion (Figure 1) in relation to age \((p=0.9)\), gender \((p=0.4)\), ethnicity \((p=0.3)\), socio-economic status (index of multiple deprivation, IMD)\(^{21} (p=0.6)\) or severity of VI \((p=0.9)\).

**Completion time**

Median completion time for both instruments was 17 minutes (range 5-107 minutes).

Overall, completion time at the hospital was significantly shorter than at home: median 14 (95% CI 12-18) versus 20 (95% CI 14-26) minutes, \(p<0.001\) (Figure 2), however, there were no associations between completion time and age \((p=0.2)\), gender \((p=0.4)\), ethnicity \(p=0.3\), or IMD \(p=0.3\).

Completion time was, however, associated with severity of VI \(p=0.007\). Those with severe VI (VA worse than logMAR 0.72 in the better eye) took significantly longer to complete the PROMs than those with VI (VA between 0.48 and 0.7), \(p=0.008\), pairwise comparison following a Bonferroni adjustment. The time taken by those with low vision did not differ statistically from those with either VI or severe VI (Figure 3).

**Missing PROM data**

Thirteen (30%) participants in the hospital setting were interrupted by being called in to see their ophthalmologist before completing the minimum 80% of items in both PROMs required for a valid score. Whilst there were greater missing values in the hospital (13% of individual item scores) than the home setting (4%), this difference was not statistically significant \(p=0.6\).

There were no associations between age \((p=0.4)\), gender \((p=0.2)\), ethnicity \((p=0.5)\), or IMD \((p=0.9)\) and amount of missing data.
The three groups defining severity of VI differed significantly with regard to missing data, $p=0.03$. The highest number of missing data (median=2 items) was for those with low vision and the lowest number of missing data (median=0 items) was for those with VA 0.48-0.7 (the mid category of VI).

Self-reported completion difficulty

Overall 97% and 86% respectively reported the VQoL_CYP and FVQ_CYP as either Easy or Very easy to complete. Fifty-seven percent of participants received some help with either the VQoL_CYP or the FVQ_CYP: 42% with reading, 17% with writing, and 45% with understanding items. Neither age nor severity of VI were related to self-reported difficulty (FVQ_CYP: $p=0.5$ for age, $p=0.7$ for severity of VI; VQoL_CYP: $p=0.5$ for age, $p=0.6$ for severity of VI), or whether participants received any help ($p=0.08$ for age, $p=0.1$ for severity of VI).

No significant differences were found in relation to difficulty rating by setting ($p=0.9$ for VQoL_CYP, $p=0.06$ for FVQ_CYP).

Self-reported preferences for format and setting of routine PROMs completion

Overall, 60% of participants self-reported a preference to complete PROMs at home. There was no clear preference regarding format, however, with 43% of participants preferring each of paper-and-pencil or electronic formats (13% indicated no preference) (Table 2).

Qualitative findings

Analysis revealed some core themes. See Supplementary Data for illustrative qualitative data.

‘Benefits to completing PROMs at home’
Participants understood that PROM completion requires cognitive investment and valued feeling comfortable, and having time and space to think, preferably in an environment where parental support could be either accessed and/or restricted. Completion at the hospital was perceived as potentially detrimental to accuracy of data by virtue of the influence of the environment and context.

‘Electronic formats are potentially burdensome’

Participants reported that electronic PROM formats could be difficult to use (e.g. screen glare, and size of text) and highlighted potential technical challenges (e.g. losing power on devices), leading to a view that electronic formats are potentially burdensome.

The subset of participants who chose to use the paper-and-pencil format, but later reported they would prefer an electronic format were probed specifically about this. Some were not aware of the alternative electronic format i.e. they had either overlooked or not been made aware by their parents of details in the study information pack.

‘Parents have their own perspectives’

The accompanying parent/caregiver of 65 (69%) participants provided their perspectives during the interviews of their children. They recognised the value of using PROMs routinely as “a good way to find out more”.

Some described uncertainty about whether their child should be “comparing” themselves to anyone - either a child with VI or one with normal vision, when completing items. Some described feeling that they needed to correct their child’s
responses, demonstrating the well-established discordance between child and parent/proxy reporting.22

DISCUSSION

We report a novel investigation of the feasibility of using PROMs in paediatric ophthalmology services, from the perspectives of the intended users, i.e. a population yet to be consulted. PROM completion at home was particularly appealing for children/young people, giving them the space and thinking time to consider their answers, and was more likely to result in a full, high quality dataset. Although participants expressed no clear preference for format, when given a free choice, they overwhelmingly chose paper-and-pencil.

This study was designed to capture patients’ preferences of PROM completion, and the feasibility of using either paper-and-pencil or electronic methods, deliberately studying a population with complex functional difficulties which impede the ability to self-report. Findings are applicable to paediatrics/child health more broadly, but specifically relevant to other conditions whose symptoms similarly impede the ability to self-report. Applying age-appropriate techniques, we achieved participation rate that compares favourably with similar research,5 6 8 enabling a sample representative of the target population.

Randomisation of participants to the PROM completion setting ensured the two groups were comparable, but some aspects of feasibility were not measured identically. PROM completion times and parental involvement were self-reported by those completing at home but directly measured at the hospital. We deliberately chose the ‘real-world’ hospital setting scenario, to assess the feasibility of this approach to routine implementation. Inevitably, this meant some participants were
interrupted. Thus differences relating to completion times may reflect to some extent our study design rather than differences by setting.

Most participants preferred to complete PROMs at home. Those who did so took significantly more time and had less missing data. This may be accounted for by less reflective or hastier completion by participants who knew they had finite time for completion. Our findings suggest that completion at home may be the best approach to collecting PROM data if the intention is to accurately capture the impact of a condition.

To ensure fully informed participation in the study, all participants assigned to the home condition received paper PROMs in the initial study packs. This may have influenced the choice of completion format, as the paper format was ‘instantly’ available. Intriguingly whilst the overwhelming majority of those given a choice of format completed the paper version, when asked directly, no clear preferences emerged. This reflects research in sighted populations showing higher participation rates are achieved by providing immediately accessible paper questionnaires alongside optional electronic formats, but that, overall, individuals tend to choose a paper version. Since we designed our electronic formats with careful consideration of the visual needs of our participants, we suggest the discordance between behaviour and reported preferences is not vision-specific but instead reflects a human tendency to choose the ‘easiest’ (i.e. most familiar and available) option. Studies with adults have shown that once familiarity with electronic formats for PROMs has been established, advantages with respect to reducing the amount of missing data can be exploited. Furthermore, sophisticated digital health applications incorporating reminder alerts to complete PROMs have demonstrated potential for addressing some of the challenges of engaging children and young
people with this format. Once these become more broadly available it will be important to re-assess both children and young people’s preferences, and the quality of data collected.

Our finding that PROM completion time had a non-linear association with severity of VI is intriguing, as the overwhelming majority of participants reported no difficulty self-completing. Therefore the observed association between completion time and acuity most likely reflects differences in time taken to self-assess rather than the practical challenges of PROM completion. Reflective responses are to be encouraged as they are the foundation of quality and meaning of PROM data. Nevertheless sufficient time for reflection needs to be balanced against the ability of children to maintain concentration on this task. Furthermore, some degree of ‘standardisation’ between and within patients, is desirable, for example to interpret changes in PROM scores over time. We suggest that routine use of child PROMs in clinical settings should include some guidance on the appropriate amount of time for completion, irrespective of format.

Our findings augment the existing literature on important and informative discordance in both generic and vision-specific self-report by children and young people versus their parents. They illustrate that parents, just like clinicians, can find the ‘disability paradox’ (whereby individuals with severe and persistent disabilities report good or excellent quality of life) challenging. This warrants consideration in ophthalmology, and other paediatric settings which serve patients who have greater reliance on parents for support for the physical act of completing PROMs. We suggest it is possible nevertheless to allow parents to support whilst still ensuring children and young people self-assess, for instance by offering parents an opportunity to comment on PROMs independently.
Child PROMs can elicit information that transforms clinicians understanding of the impact of conditions, and any treatment, on their patients. The use of PROMs in research contexts, in particular in randomised controlled trials, is now standard practice. Our findings - using child-vision PROMs and a population with VI as a model - suggest that it is feasible to implement their routine use in paediatric practice. Exactly how this is done will, naturally, vary by the characteristics of the service, including whether/which PROMs are already being implemented. Our findings regarding completion time, missing data, preferences regarding setting and format and parental influence are useful to further research and implementation.
‘What is already known on this topic’

- Child-appropriate patient-reported outcome measures (PROMs) are available for a number of paediatric specialties, and increasingly valued as adjuncts to routine clinical assessments.
- PROMs are particularly useful in chronic childhood conditions, for detecting the impact of age- and disease-specific challenges encountered as patients grow up.

‘What this study adds’

- Implementing PROMs in routine practice for visually impaired children and young people is feasible, with high completion rates, reasonable completion times, and limited missing data.
- A clear preference for PROM completion at home and in paper-and-pencil format emerged, suggesting this as the optimal approach for collecting complete, high-quality datasets.
- This approach may be successful in other groups with chronic conditions and/or functional limitations that impact ability to self-report in a time pressured clinical environment.
ACKNOWLEDGEMENTS

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REFERENCES


FIGURE LEGENDS

Figure 1. Flowchart showing distribution of participants by condition.

Figure 2. Kaplan-Meier plot showing completion time (in minutes) stratified by setting (home versus at the hospital). Participants who were interrupted during PROM completion are censored.

Figure 3. Kaplan-Meier plots of completion time (in minutes) stratified by severity of VI. Participants who were interrupted during PROM completion are censored.
Table 1. Demographic and clinical characteristics of 93 participants stratified by setting and format.

<table>
<thead>
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<th>Characteristic</th>
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<th>Home/Electronic (n = 1)</th>
<th>Clinic/Paper (n = 23)</th>
<th>Clinic/Electronic (n = 21)</th>
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<td></td>
</tr>
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<td>-</td>
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<td>2 (22.2)</td>
</tr>
<tr>
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<td>4 (40.0)</td>
<td>1 (10.0)</td>
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<tr>
<td>10</td>
<td>7 (35.0)</td>
<td>-</td>
<td>6 (30.0)</td>
<td>7 (35.0)</td>
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<td>-</td>
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<td>-</td>
<td>1 (16.7)</td>
<td>2 (33.3)</td>
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<tr>
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<td>14</td>
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<td>3 (25.0)</td>
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<tr>
<td><strong>Gender</strong></td>
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<td>14 (29.2)</td>
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<td>12 (26.7)</td>
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<tr>
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<td>1 (2.0)</td>
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<td>9 (17.7)</td>
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<td>White other (e.g. African, Polish, Turkish)</td>
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<td>1 (20.0)</td>
<td>1 (20.0)</td>
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<tr>
<td>Black (British, African, Caribbean)</td>
<td>3 (37.5)</td>
<td>-</td>
<td>3 (37.5)</td>
<td>2 (25.0)</td>
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<tr>
<td>Asian (Indian, Bangladeshi, Pakistani)</td>
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<td>-</td>
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<td>1 (14.3)</td>
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<tr>
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</tr>
<tr>
<td>1: most deprived</td>
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<td>-</td>
<td>2 (14.3)</td>
<td>2 (14.3)</td>
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<tr>
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<td>8 (53.3)</td>
<td>-</td>
<td>2 (13.3)</td>
<td>5 (33.3)</td>
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<td>4</td>
<td>13 (61.9)</td>
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<td>5 (23.8)</td>
<td>2 (9.5)</td>
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<tr>
<td>5: least deprived</td>
<td>9 (40.9)</td>
<td>-</td>
<td>8 (36.4)</td>
<td>5 (22.7)</td>
</tr>
<tr>
<td>Missing</td>
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<td>-</td>
<td>1 (50.0)</td>
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<tr>
<td><strong>Severity of visual impairment</strong></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>LV: logMAR ≤ 0.46</td>
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<td>-</td>
<td>9 (23.1)</td>
<td>9 (23.1)</td>
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<tr>
<td>VI1: logMAR 0.48-0.70</td>
<td>11 (47.8)</td>
<td>1 (4.4)</td>
<td>7 (30.4)</td>
<td>4 (17.4)</td>
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<tr>
<td>-----------------------</td>
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</tr>
<tr>
<td>VI2: logMAR 0.72-1.00</td>
<td>9 (42.7)</td>
<td>-</td>
<td>7 (33.3)</td>
<td>5 (23.8)</td>
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<td>SVI: logMAR 1.02-1.30</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Blind: logMAR ≥ 1.32</td>
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<td>-</td>
<td>-</td>
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Table 2. Participants’ self-reported preferences relating to completion setting and format of PROMs

<table>
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<th>Format (n(%)</th>
<th>Home (n(%))</th>
<th>Hospital (n(%))</th>
<th>School (n(%)</th>
<th>Public transport (n(%)</th>
<th>No preference (n(%)</th>
<th>Total (n(%)</th>
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<tr>
<td>Paper</td>
<td>27 (31.0)</td>
<td>6 (6.9)</td>
<td>0</td>
<td>0</td>
<td>4 (4.6)</td>
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<td>Electronic</td>
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<td>10 (11.5)</td>
<td>3 (3.5)</td>
<td>1 (1.2)</td>
<td>6 (6.9)</td>
<td>37 (42.5)</td>
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<td>Braille</td>
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<td>0</td>
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<tr>
<td>No preference</td>
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<td>1 (1.2)</td>
<td>2 (2.3)</td>
<td>0</td>
<td>2 (2.3)</td>
<td>11 (12.6)</td>
</tr>
<tr>
<td>Total</td>
<td>52 (59.8)</td>
<td>17 (19.5)</td>
<td>5 (5.8)</td>
<td>1 (1.2)</td>
<td>12 (13.8)</td>
<td>87* (100)</td>
</tr>
</tbody>
</table>

* 6 participants excluded due to missing self-report data.