

“How easily could you obtain proof of diagnosis for your medical condition?” Feedback from individuals with chronic medical conditions on a digital diagnosis validation feature

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Background & Objectives

Real-world studies are of increasing importance in the provision of data to evaluate treatment value and effectiveness in clinical practice¹. Diagnosis validation is a key aspect of the recruitment process in real-world patient- and caregiver-reported studies where recruitment is not conducted through clinical sites^{2,3}; it ensures participants are eligible to take part in studies based on a diagnosis of the target disease, or receiving a particular treatment.

In circumstances where a patient population is hard to reach – for instance, in rare disease studies – the recruitment and validation process must be carefully planned so that recruitment numbers from a typically small and geographically dispersed patient population are maximized, while maintaining confidence that participants have a genuine diagnosis.

There are various methodologies that can be used for diagnosis validation – the methodology selected is dependent on the design of the study, patient population, intended audience, and recruitment source. One source of diagnosis validation, when proof of diagnosis cannot be sought from a clinician, is requesting that prospective participants provide a diagnosis letter or proof of medication packaging during study enrollment (see **Figure 1**).

Diagnosis validation features have been implemented in digital patient- and caregiver-reported studies, embedded as part of the study enrollment process. Whilst these features have been used by study participants, patient attitudes towards them as well as ease of use and overall participant experience have not been explored. The objective of this project was to explore perceptions of a digital diagnosis validation feature.

Figure 1 An example diagnosis validation feature shared with respondents

Methods

Individuals with a range of chronic medical conditions completed a web-based survey comprising questions on demographics, medical diagnosis, and their perceptions of using a digital diagnosis validation feature as part of enrollment in a research study.

Results

Twenty-two individuals (mean age: 52, range: 28–74) completed the survey. Over half of respondents (52%; n=11/21 who responded to this question) reported that they could obtain proof of their medical diagnosis easily if required; 38% (n=8) stated that it would be with difficulty (see **Figure 2**), with the main reason reported being poor cooperation from healthcare facilities in obtaining this information.

Of those reporting that they could obtain proof easily, the majority (n=7, 64%) already had proof of diagnosis; of those reporting that they would have difficulty obtaining proof, the majority (n=6, 75%) did not currently have it. 50% (n=9/18 who responded to this question) and 33% (n=6) of respondents stated that they would keep the proof of their diagnosis as a hard copy of a document (physically) or digitally, respectively (see **Figure 3**).

Ninety percent of respondents (n=19/21 who responded to this question) stated they would obtain proof from their surgery or specialist if required (see **Figure 4**). The majority of respondents (86%; n=19/22 who responded to this question) reported that they would be comfortable sharing a copy of their medical diagnosis as part of registration to a research study. Sixty-two percent of respondents (n=13/21 who responded to this question) reported that they would find it easy to use an upload feature to share their medical diagnosis (see **Figure 5**).

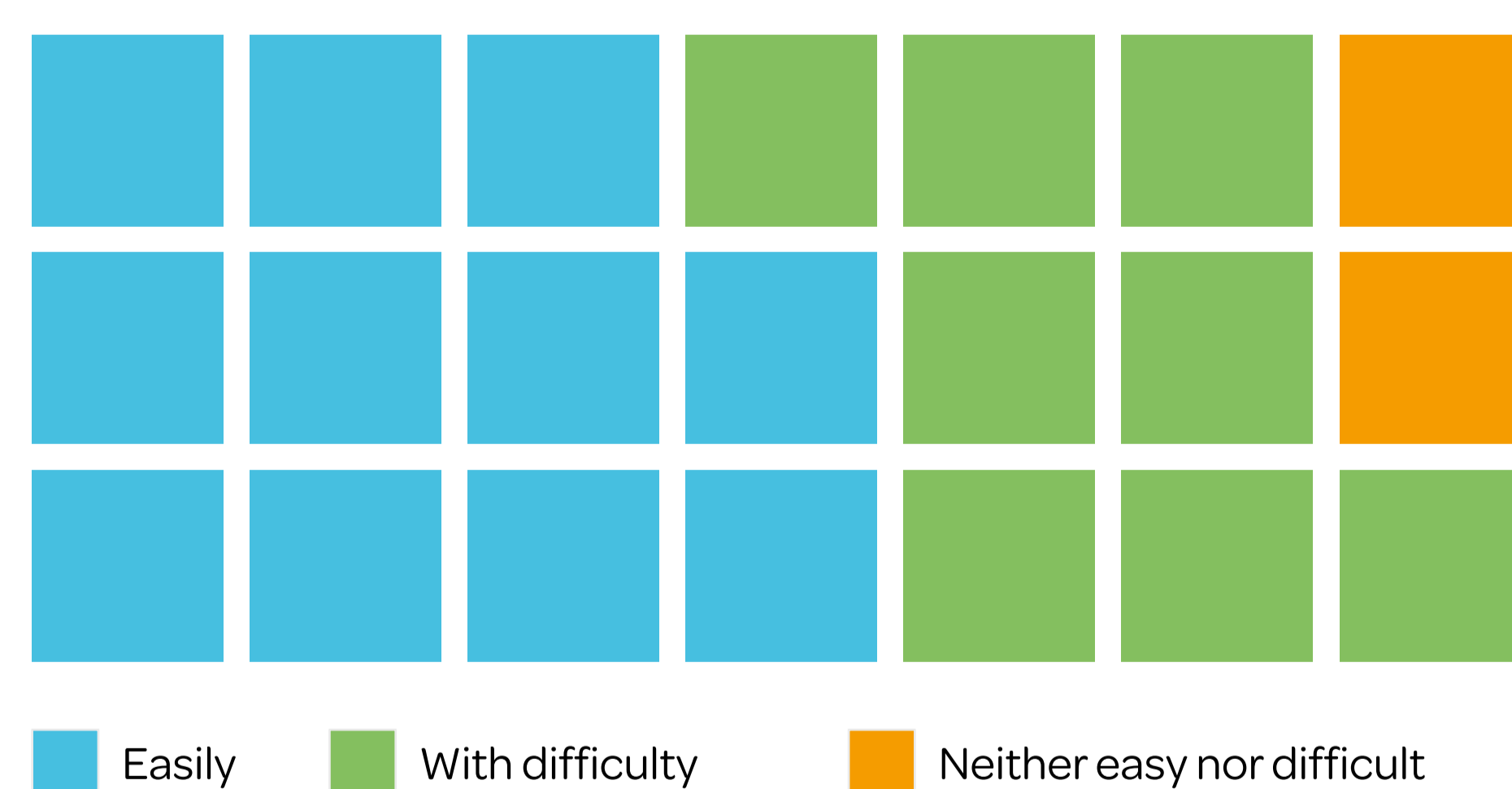


Figure 2 Responses to “How easily could you obtain proof of diagnosis for your medical condition?” (n=21)

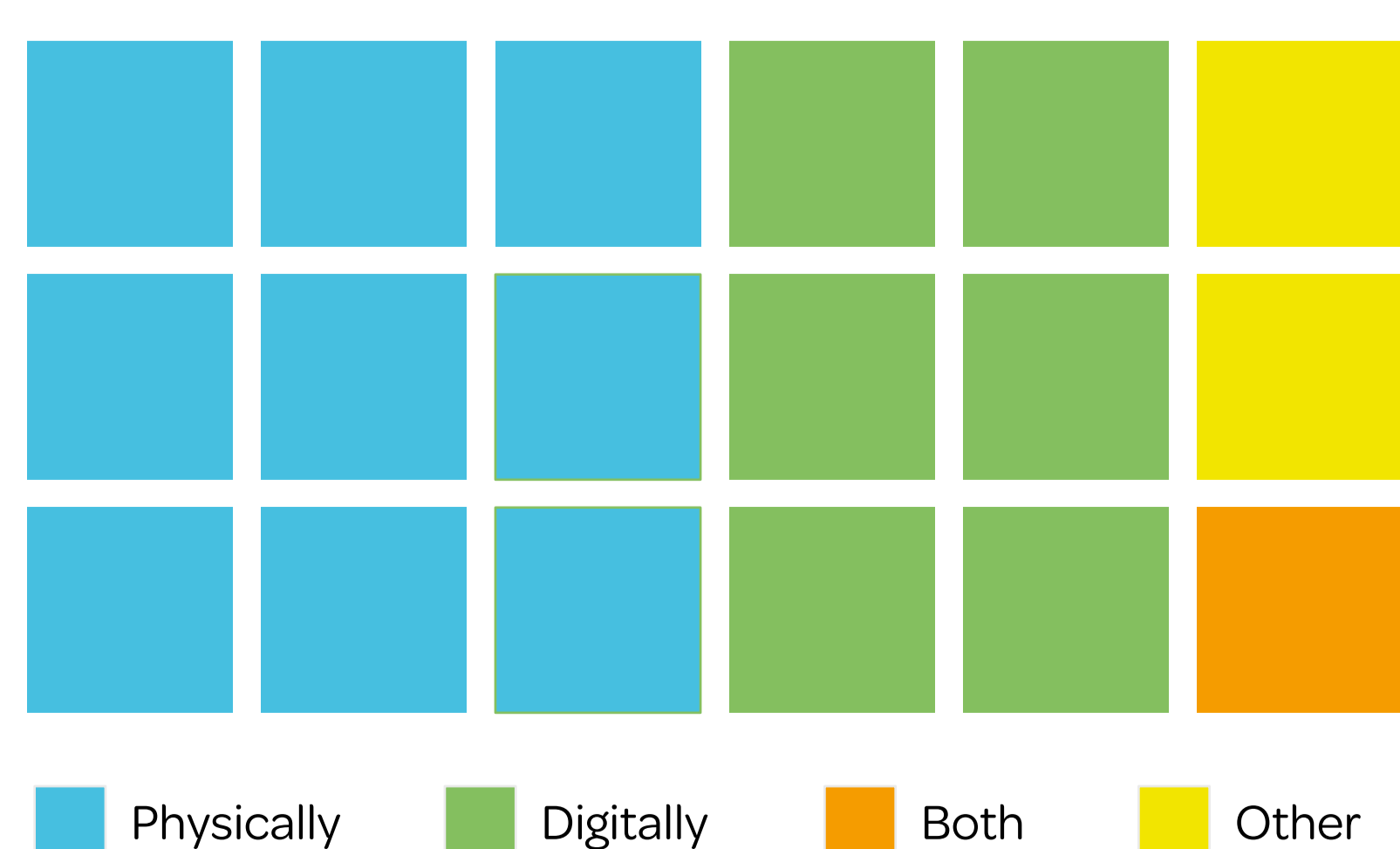


Figure 3 Responses to “Where do/would you keep it (the proof of your medical diagnosis)?” (n=18)

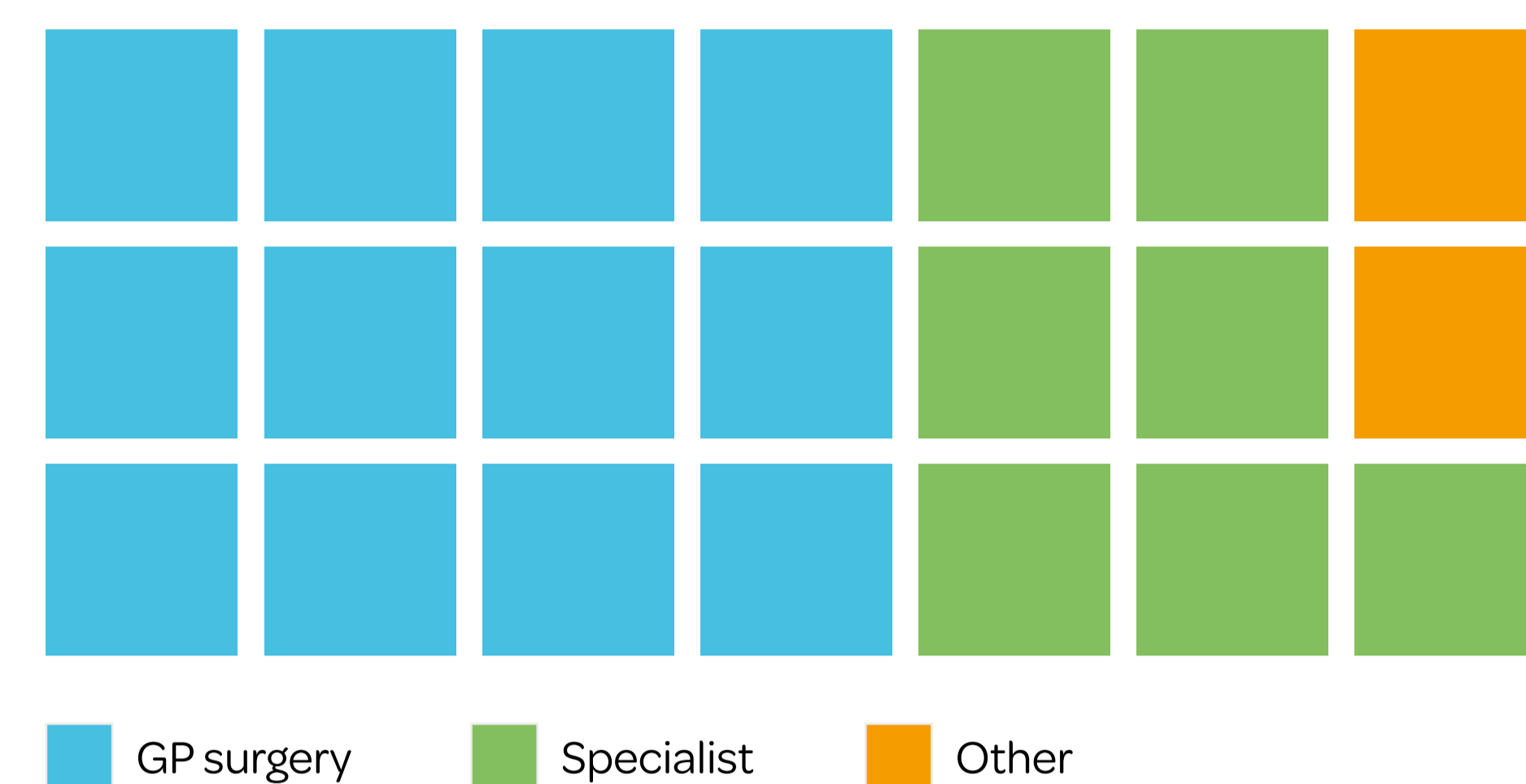


Figure 4 Responses to “Where did/would you get proof of your diagnosis?” (n=21)

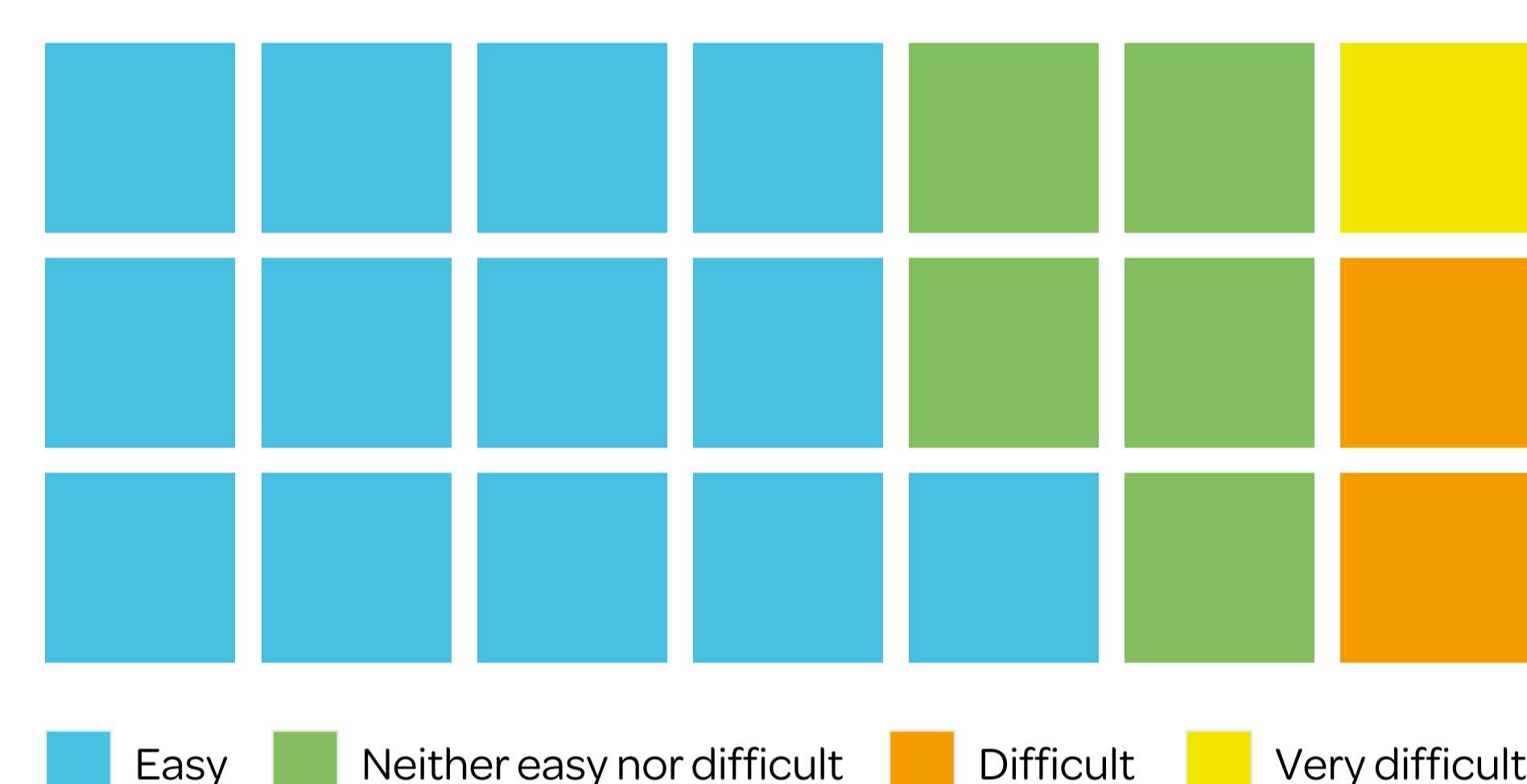


Figure 5 Responses to “How would you find it to use the upload feature?” (n=21)

Discussion & Conclusions

Over half of the respondents believed they could obtain proof of diagnosis easily and, of that group, the majority already had proof of their diagnosis available. This suggests that a digital study feature in which participants are required to upload proof of their diagnosis could be adapted in patient populations without significant issues. Furthermore, the majority of respondents reported that they would find the document-upload feature easy to use.

Attitudes towards sharing medical information as part of study registration were generally positive. Employing such features can result in a reliable alternative to clinical site-based recruitment for real-world patient- and caregiver-reported studies; this has been observed in the ongoing adult-onset leukoencephalopathy with axonal spheroids and pigmented glia patient registry⁴.

References

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