Successful integration of an automated Patient Reported Outcome Measure within a hospital electronic patient record

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Abstract

Objectives

The objective of this evaluation was to assess the feasibility of implementing a fully-integrated, automated, electronic Patient Reported Outcome Measures (ePROM) system into a hospital Electronic Patient Record (EPR) (hospital-based clinical record). Additional objectives included evaluating the effect of the system on PROM completion rates and investigating the acceptability of the ePROM.

Methods

The evaluation was conducted in a rheumatology clinic in a specialist children's hospital in the UK. Paper-based Childhood Health Assessment Questionnaire (CHAQ) PROMs were already used in the clinic and an EPR was the main hospital information system. The technical feasibility of introducing the ePROM technology was assessed using a case study approach; the effect of the system on PROM completion rates was investigated using a before-after design; and acceptability was assessed using semi-structured questionnaires and a focus group.

Results

An automated and integrated ePROM system was successfully implemented in April 2021. Following implementation approximately 500 automated SMS invitations to complete ePROMs were sent to care-givers each month. PROM completion rates increased from 33/100 (33%) to 47/65 (72%) after the introduction of the ePROM system (chi-square = 11.51; $p < 0.05$). The ePROM system was highly acceptable to patients and clinical staff. Some clinical staff expressed a concern that an electronic system may represent a barrier to care for families with more limited resources.

Conclusions

High levels of automation and integration with existing technology systems seemed to be key contextual factors associated with the successful implementation and adoption of the ePROM intervention in a paediatric rheumatology clinic.

Key Words: Medical informatics, Patient Reported Outcome Measures, rheumatology, quality improvement, paediatrics

Key Messages

- The development of an automated, fully integrated electronic Patient Reported Outcome Measurement (ePROM) system was feasible.
- The ePROM system improved PROM completion and documentation rates.
- The ePROM system was highly acceptable to health professionals and patients.

Lay summary

What does this mean for patients?

We conducted this study to find out whether it would be practical to use an electronic version of a health questionnaire to collect information about young people's symptoms and wellbeing ahead of planned, hospital rheumatology clinics. The aim was to send and upload the completed questionnaires into the patients' electronic health records using a new automated system. We wanted to find out whether this would increase the frequency with which the questionnaire information was recorded in the health records and to understand whether patients and healthcare professionals would find the electronic system acceptable to use. The system was successfully set up and increased the frequency with which the questionnaire results were recorded in patient's health records from 33% to 72%. The study also identified that patients, their families, and healthcare professionals generally found the system easy to access and to use. Overall, we think this study highlights that there is potential to use systems like this to improve the quality of information that hospital systems can collect from their patients. This can lead to better understanding of symptoms, contributing to the best possible care.

Introduction

Patient Reported Outcome Measures (PROMs) are instruments for assessing health conditions from a patient or caregiver's perspective. PROMs are most frequently designed as standardised, validated questionnaires and they can be used to measure the health effects (outcomes) that are of most importance to patients; these might include levels of physical or social functioning, severity of symptoms, or general wellbeing (1).

PROMs have been key to improving the quality of rheumatology research(2) and are also widely used in routine clinical care(1). In research settings PROMs can help to identify the treatments that offer the most beneficial effects. In routine clinical care they may enable healthcare workers and patients to track the effects of treatments, and may enable more objective audits of the services provided at different healthcare organisations (1, 3, 4).

The Child Health Assessment Questionnaire (CHAQ) is a 36 item PROM that has been validated for assessing functional outcomes, general well-being, and pain(5). The rheumatology team at Alder Hey Children's NHS Foundation Trust, a specialist children's hospital in the United Kingdom, have historically used the CHAQ(6) as a routine standard of care in outpatient clinic consultations.

However, informal interviews with Health Care Professionals (HCPs) and patient groups highlighted issues that negatively impacted CHAQ completion and documentation rates. These factors included: paper CHAQs not being handed out to all eligible patients at appointments, the need for healthcare professionals (HCPs) to manually score and document completed assessments, lack of access to paper CHAQs outside clinic settings, and a risk of calculation and transcription errors associated with manually scoring and documenting results into the hospital's Electronic Patient Record (EPR).

An electronic PROM (ePROM) system was identified as having the potential to reduce the impact of these issues. This evaluation was therefore conducted with three objectives:

1. To investigate the feasibility of implementing an ePROM system with automated generation of requests, and automated scoring and integration of data into the EPR
2. To study the effects of using the system on CHAQ completion rates
3. To evaluate the acceptability of the system

Methods

The methods used included: a descriptive case study to investigate the feasibility of implementing the technology; a before-after study to evaluate the effects on CHAQ completion rates; and surveys and focus groups to gather data about the acceptability of the intervention.

An evaluation protocol (Supplementary Data S1, available at *Rheumatology Advances in Practice* online) was registered with the Alder Hey Children's NHS Foundation Trust Governance and Assurance department. NHS Health Research Authority guidance (7) indicated that Research Ethics Committee approval and formal written consent were not required as the investigation constituted a service evaluation exercise which used anonymised data. The Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines(8) were used to structure this report.

Feasibility case study

The technical feasibility case study was conducted using data gathered from direct observations, technical specification reports and schemas, meeting notes, internal reports and internal presentations. The case study report was developed using SQUIRE 2.0(8) and Health Information Technology (HIT) (9) reporting guidelines.

CHAQ completion rates

The effect on CHAQ completion rates was investigated using a before-after study design. Data were identified from manual reviews of the clinical records of children who attended scheduled

rheumatology appointments in a two-week period before (July 2019) and after (July 2021) the introduction of the ePROM system.

In the before period, clinical records were defined as demonstrating a completed CHAQ if they included any documentation of a CHAQ score. In the after period the records were identified as demonstrating a completed CHAQ assessment if they included a CHAQ score as structured data against a specific CHAQ score query in the EPR *and* as an appropriately filed electronic copy of the completed CHAQ questionnaire. Chi-square testing was used to analyse whether differences in completion rate were statistically significant.

Acceptability of the ePROM intervention

The acceptability of the intervention was evaluated using a patient survey, and a focus group and survey of HCPs.

Patient survey

The Patient and Parent ePROM Questionnaire was developed by the evaluation team based on findings from systematic reviews of HIT implementation research (9, 10). These reviews identified key constructs that are associated with successful HIT implementations including attitudes and acceptance of health technologies and the accessibility of HIT systems. The questionnaire items were developed through iterative discussion rounds by the evaluation team and questionnaires were administered to families who were attending outpatient clinics in July 2021 (in paper format to avoid excluding families who did not have access to electronic questionnaires). The data from these questionnaires were analysed using descriptive statistical methods. A copy of the questionnaire is available in Supplementary Table S1, available at *Rheumatology Advances in Practice* online.

Focus group with healthcare professionals

A focus group was conducted with rheumatology HCPs. The focus group method was selected to encourage dialogue highlighting HCP's experiences of using the ePROM system and was conducted as part of a scheduled team meeting held online (MS Teams software). Two investigators (MN and GC) provided a brief presentation introducing the objectives of the ePROM project and describing the purpose of the focus group (slides presented as Supplementary Figure S1, available at *Rheumatology Advances in Practice* online). MN led a guided discussion covering general observations relating to the ePROM system followed by a directed discussion of its strengths, weaknesses and unintended consequences anddata were collected from recorded meeting minutes and field notes. MN and GC then led an inductive analysis ; coding and categorising the data into themes that were described by the HCPs.

Survey of HCPs

The Technology Acceptance Model 2 (TAM2) questionnaire(11, 12) was used to assess the acceptability of the ePROM system to HCPs. TAM2 has been validated for use in workplace settings and is designed to measure key constructs that predict usage intentions and the acceptance of workplace information technology systems(13). The items are measured using seven point Likert scales. Invitations to complete the questionnaire were sent electronically to 29 members of the rheumatology MDT on two occasions in July 2021. The results of the survey were analysed using descriptive statistical methods.

Results

Feasibility case study

Evaluation setting and existing Health Information Technology Infrastructure

The main clinical information system used in the Trust throughout the study period was an Electronic Patient Record (EPR) (MEDITECH V6.08, Boston, USA). EPR functions included reviewing and scheduling appointments, documenting consultations, and requesting and reviewing medication and investigations.

Paper-based CHAQ PROM assessments had been used as a part of routine clinical care within the rheumatology department on a long-term basis. Previously, paper questionnaires were provided to patients for completion in the clinic waiting room and were then passed to clinical staff for scoring/transcription during the consultation.

Development of the ePROM system

The ePROM system was developed by clinical leads from the Rheumatology team, representatives from the Alder Hey Information Technology team, and an independent technology provider (AireLogic, Leeds, UK). Consultation with patient groups and literature reviews identified web-links within SMSs as an acceptable and accessible approach for contacting families(14). Literature reviews and consultations with HCPs who used PROMs highlighted automation and integration with existing HIT systems as key factors for improving the chances of successfully implementing the system (15-17).

A Data Protection Impact Assessment (DPIA) was completed and presented to the Trust's Information Governance committee who approved the project in October 2019.

The system was developed with the following technical features (see Figure 1 and Supplementary Figure S2 (available at *Rheumatology Advances in Practice* online) for screenshots of patient and clinician user interfaces):

1. A daily report was generated to identify patients scheduled to attend rheumatology clinics (Meditech EPR reporting module)
2. Patient data were pseudonymised (Aire Glu, Aire Logic, Leeds, UK) in order to generate a unique web address (Uniform Resource Locator/URL)
3. The URL link to the online CHAQ assessment was delivered to the relevant mobile phone number listed in the patient record via a Short Messenger Service (SMS) text message (CHAQ assessments provide by Forms4Health software, Aire Logic, Leeds, UK)
4. Completed CHAQs were re-associated with the relevant patient record (AireGlu, Aire Logic, Leeds UK) before being stored against the relevant clinical episode/visit.
5. Numeric CHAQ scores were calculated and visible to clinicians in electronic forms used in the rheumatology outpatient documentation, and pdf versions of the assessments were also stored against the patient visit.

No formal training was provided to either HCPs or families as the system was designed to be as automated and accessible as possible.

Implementation of the ePROM system

The ePROM system was launched in March 2021 with approximately 500 invitations to complete ePROMs sent on a monthly basis. The SMSs included explanatory text and a contact telephone number for the rheumatology team, and the introductory text on the electronic CHAQ assessments included a link to an information page on the Alder Hey website. **Error! Reference source not found.** below illustrates these aspects of the system.

CHAQ completion rates

Use of the ePROM system was associated with a statistically significant increase in the CHAQ completion rate. In the period before the implementation of the system, 33/100 (33%) assessed records included documentation of a CHAQ score, this increased to 47/65 (72%) after the introduction of the ePROM system (chi-square = 11.51; $p < 0.05$) (see Figure 2).

Acceptability of the ePROM system

Acceptability to patients and their carers

The Patient and Parent ePROM questionnaire was completed by 24 respondents (no formal record of how many families declined to complete the questionnaire was captured). Respondents indicated positive baseline attitudes towards using health technologies (median response to "happy to use new tech for child's healthcare" question = 5 (strongly agree), Interquartile range (IQR) = 0) and that the system was accessible to them (median responses to questionnaire items 2-4 = 5 (strongly agree), (IQR = 0)).

Respondents also indicated that they would find it acceptable to use the ePROM system again (median response to questionnaire item 6 = 5 (strongly agree), (IQR = 0)) and a majority reported preferring to complete ePROMs more frequently (n = 19/24 (79.2%)). Respondents also perceived that the system was useful for their child's care (median response to questionnaire item 7 = 5 (strongly agree), (IQR = 0)). The full responses to the questionnaire are summarised in Supplementary Table S2, available at *Rheumatology Advances in Practice* online.

Acceptability to Clinical Staff- Results of Focus Group Discussion

A focus group was conducted with 10 rheumatology HCPs including consultant physicians, nurse specialists and occupational therapists on the 6th July 2021. The key themes identified from the discussion included positive feedback from families, more time for discussion during the consultation and an improved quality of clinical data. Focus group participants and themes can be found in Supplementary Tables S3 and S4, available at *Rheumatology Advances in Practice* online.

Negative aspects of using ePROMs included extra phone calls to the administrative team for clarification about wording used in the CHAQ questionnaire and concerns that families with more limited access to financial resources may experience difficulties with accessing the system. The key themes identified in the focus group have been outlined in Table 1.

Table 1. Summary of themes identified from HCP focus group discussion

Theme identified from analysis of focus group discussion	Illustrative quotes
Generally positive feedback	*I really like it*
	I find it really helpful
	I think this is working really, really well
Time saving	*We don't have to spend any time calculating the CHAQ score*
Improved data quality	*It's fantastic [that CHAQ data] is captured within reports on Meditech [the hospital EPR]*
	It gives the physiotherapists a baseline that they can work to and then they can repeat the CHAQ - I've found that incredibly helpful to get a sense of where the patient's at
	I'm extremely excited about the fact that it [the CHAQ data] contributes to a set of core JIA criteria [data]
	I know in my own practice I haven't been as robust as others about documenting and collecting the CHAQ when I've had it on paper so I think my completion rate for the JIA core set [of data], you know, it's going to improve significantly because of this
	That it's not just a number anymore, and the it pulls into the core set [JIA cores set of data] is fantastic
Access to CHAQ data ahead of clinic consultation	*I found it helps to inform my clinical consultation both in terms of the report and in terms of the score and especially if I've seen that in advance of the patient coming in*
	Being able to see the CHAQ before clinic and realise where there's issues
Concerns and queries relating to when the ePROM messages are sent to families and carers	*The patients who are in[to clinic] first thing...who are getting the CHAQ at half past eight [on the morning of the clinic appointment] are finding it more difficult [to complete the CHAQ before the appointment]*
	Just in terms of patients ringing me I've had a few different scenarios of wanting to know if they can complete it over the weekend if their appointments on the Monday will you get it back in time.

Concerns about the "digital divide" or equal access to digital systems	*Are there any protections in place to ensure that some families have not been excluded or discriminated against and the potential bias that this could create if you only get the more kind of well-off families being able to complete these questionnaires and are those questionnaires then going to feed back into data that we're going to analyse*
	[the] digital divide and inequality could be a real factor
	Families are offered paper copies [at the moment] but the more we use electronic systems the less families may be offered paper versions

Acceptability to HCPs – Results of Technology Acceptance Model 2 (TAM2) Survey

HCPs (n = 7; respondents included consultants, nurse specialists and occupational therapists) scored the ePROM highly across all TAM2 domains including "Perceived Usefulness" (median response = 7 (strong agreement); IQR = 0.25) "Output Quality" (median response = 7 (strong agreement); IQR = 1 and "Perceived ease of use" (median response = 7, IQR = 0). The full responses to the questionnaire are summarised in Supplementary Table S5, available at *Rheumatology Advances in Practice* online.

Discussion

This evaluation demonstrates the feasibility of integrating an automated ePROM system within an NHS EPR. The ePROM system was associated with an improvement in data quality and was highly acceptable to patients and HCPs. The system successfully resolved previous issues associated with the use of paper-based PROMs including time-consuming completion and scoring processes and the risks of transcription and misfiling errors. The system also removed described barriers to the completion of PROMs away from hospital settings. High levels of automation and integration with existing Health IT systems were contextual factors that may have contributed to these successes. Potential unintended consequences of using the system included hypothetical concerns about the risk of families being excluded from using digital systems due to resource constraints.

These findings suggest that ePROMs may help clinical teams to gain improved insights into the health status of their patients. Improvements in data quality may also help to improve audit and commissioning processes and may enable the integration of research into routine care, through the use of standardised, core-data sets than can be collected routinely in clinical settings (18).

Strengths of this evaluation include the use of mixed-methods to identify contextual factors that may have contributed to the positive findings described in the report and the large effect size in relation to the change in PROM completion rates.Limitations include its single centre design, the use of observational methods, and the use of an unvalidated Patient and Parent ePROM questionnaire for testing the acceptability of the system which may have been completed by a non-representative sample of families.

Future research approaches could therefore include evaluating the ePROM technology in additional settings; either using the CHAQ in an alternative centre or by using alternative questionnaires to assess additional PROM or Patient Reported Experience Measures (PREM). Additional opportunities could include consideration of whether ePROM data may contribute to decisions about how frequently to arrange follow up appointments for individuals.

Conclusion

This evaluation confirmed the technical feasibility of integrating an electronic PROM directly into an NHS EPR system. Introduction of the ePROM was associated with improved data quality and was highly acceptable to patients and HCPs.

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Competing Interest Statement

The authors have no conflicts of interest to declare.

References

1. Nelson EC, Eftimovska E, Lind C, Hager A, Wasson JH, Lindblad S. Patient reported outcome measures in practice. BMJ : British Medical Journal. 2015;350:g7818.
2. Tugwell P, Boers M, Brooks P, Simon L, Strand V, Idzerda L. OMERACT: an international initiative to improve outcome measurement in rheumatology. Trials. 2007;8:38.
3. Black N. Patient reported outcome measures could help transform healthcare. BMJ (Clinical research ed). 2013;346.
4. Marshall S, Haywood K, Fitzpatrick R. Impact of patient-reported outcome measures on routine practice: a structured review. Journal of evaluation in clinical practice. 2006;12(5):559-68.
5. Singh G, Athreya BH, Fries JF, Goldsmith DP. Measurement of health status in children with juvenile rheumatoid arthritis. Arthritis & Rheumatism. 1994;37(12):1761-9.
6. Nugent J, Ruperto N, Grainger J, Machado C, Sawhney S, Baildam E, et al. The British version of the childhood health assessment questionnaire (CHAQ) and the child health questionnaire (CHQ). Clin Exp Rheumatol. 2001;19(4; SUPP/23):S163-S7.
7. Authority NHR. NHS HRA Decision Tool London, UK: NHS Health Research Authority; 2017 [Available from: http://www.hra-decisiontools.org.uk/research/.
8. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. American Journal of Critical Care. 2015;24(6):466-73.
9. Neame MT, Sefton G, Roberts M, Harkness D, Sinha IP, Hawcutt DB. Evaluating Health Information Technologies: A systematic review of framework recommendations. International Journal of Medical Informatics. 2020:104247.
10. Cresswell K, Williams R, Sheikh A. Developing and Applying a Formative Evaluation Framework for Health Information Technology Implementations: Qualitative Investigation. J Med Internet Res. 2020;22(6):e15068.
11. Venkatesh V, Davis FD. A theoretical extension of the technology acceptance model: Four longitudinal field studies. Management science. 2000;46(2):186-204.
12. Venkatesh V, Bala H. Technology acceptance model 3 and a research agenda on interventions. Decision sciences. 2008;39(2):273-315.
13. Turner M, Kitchenham B, Brereton P, Charters S, Budgen D. Does the technology acceptance model predict actual use? A systematic literature review. Information and software technology. 2010;52(5):463-79.
14. Marcano Belisario JS, Jamsek J, Huckvale K, O'Donoghue J, Morrison CP, Car J. Comparison of self-administered survey questionnaire responses collected using mobile apps versus other methods. Cochrane Database of Systematic Reviews. 2015(7).
15. Yen P-Y, Bakken S. Review of health information technology usability study methodologies. Journal of the American Medical Informatics Association : JAMIA. 2012;19(3):413-22.
16. Pelayo S, Ong M. Human Factors and Ergonomics in the Design of Health Information Technology: Trends and Progress in 2014. Yearbook of medical informatics. 2015;10(1):75-8.
17. Carayon P, Alyousef B, Hoonakker P, Hundt AS, Cartmill R, Tomcavage J, et al. Challenges to care coordination posed by the use of multiple health IT applications. Work (Reading, Mass). 2012;41.
18. McErlane F, Armitt G, Cobb J, Bailey K, Cleary G, Douglas S, et al. CAPTURE-JIA: a consensus-derived core dataset to improve clinical care for children and young people with juvenile idiopathic arthritis. Rheumatology. 2020;59(1):137-45.

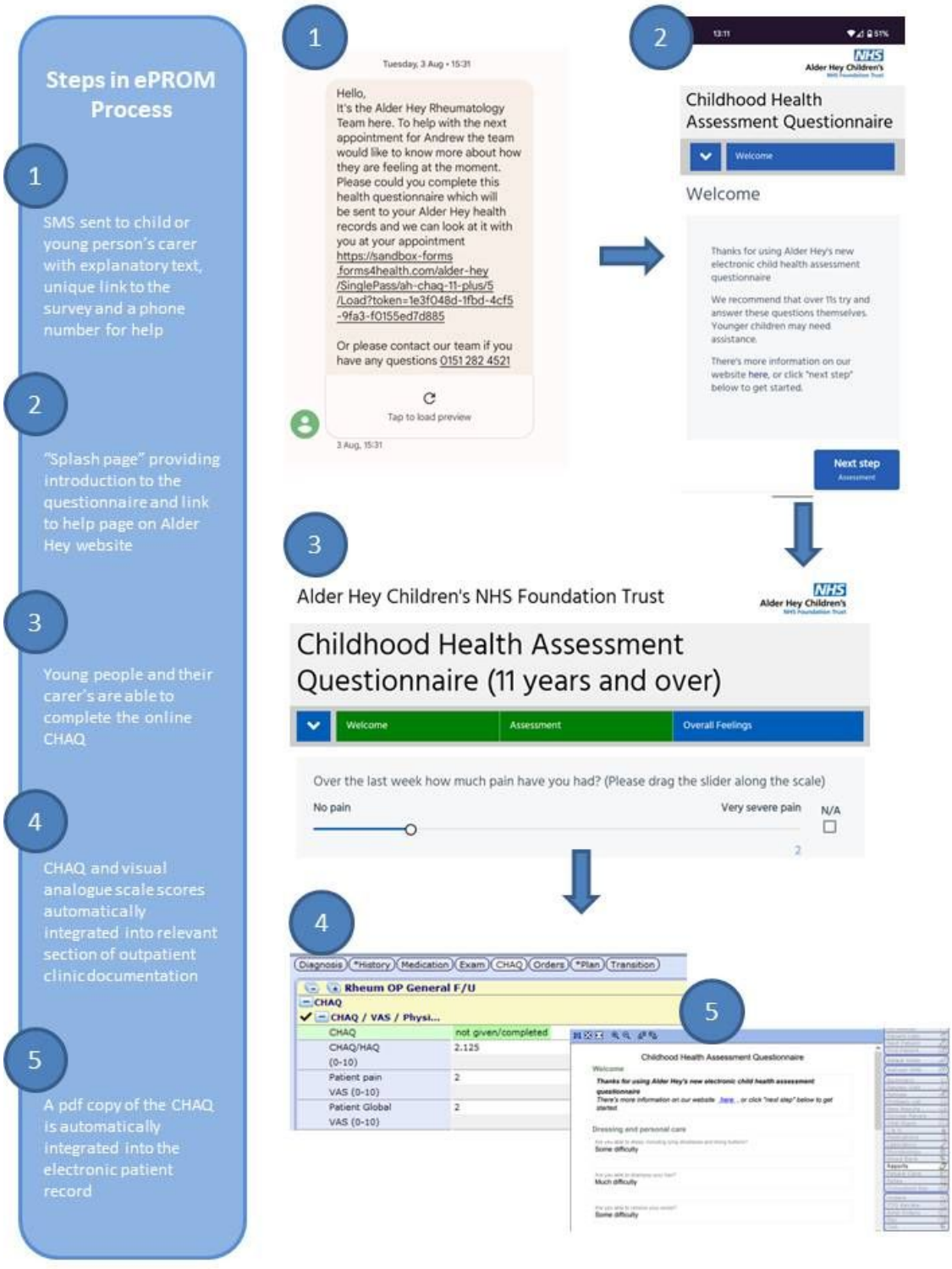

Figure 1. Schema and Screenshots illustrating the functions of the ePROM system.

CHAQ: Childhood Health Assessment Questionnaire.

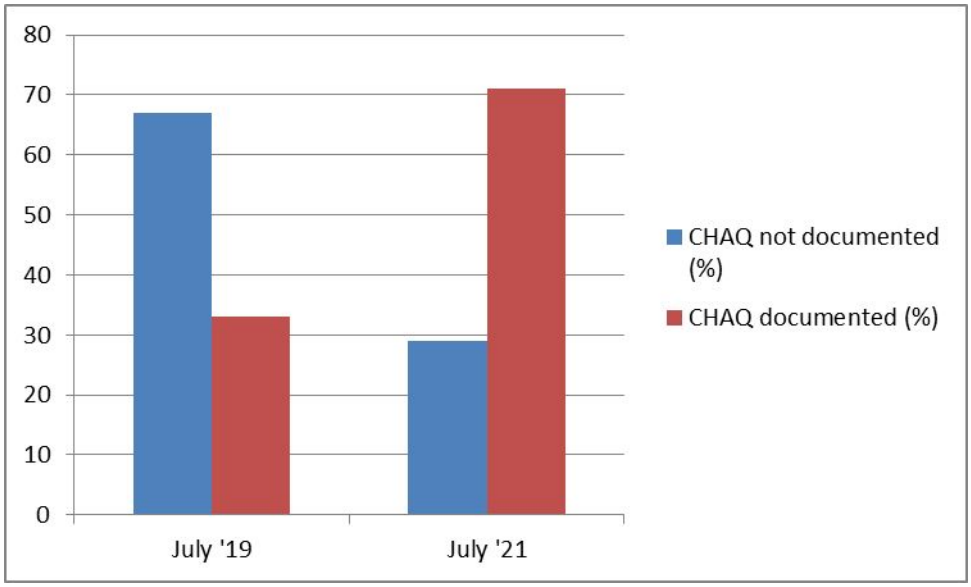

Figure 2. Bar chart demonstrating CHAQ completion rates before and after the introduction of the ePROM system. CHAQ: Childhood Health Assessment Questionnaire.

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Infections: Infections, including serious infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be assessed prior to initiating in patients with risk factors for infections (see SmPC). Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. Treatment should be interrupted if the patient is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. Tuberculosis: Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. Viral reactivation: Cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster, filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. Malignancy: Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). Fertility: In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. Haematological abnormalities: Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) <1 × 10^9 cells/L, ALC <0.5 × 10^9 cells/L or haemoglobin <8 g/dL. Temporarily stop therapy if these values are observed during routine patient management. Vaccinations: Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. Lipids: Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). Cardiovascular risk: Rheumatoid arthritis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. Venous thromboembolism: Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged immobilisation. 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Serious side effects: See SmPC for full information **Legal category:** POM **Pack:** 30 film-coated tablets/bottle **Price:** UK Basic NHS cost: £863.10 **Marketing authorisation number(s):** Great Britain Jyseleca 100mg film-coated tablets PLGB 42147/0001 Jyseleca 200mg film-coated tablets PLGB 42147/0002 Northern Ireland Jyseleca 100mg film-coated tablets EU/1/20/1480/001 EU/1/20/1480/002 Jyseleca 200mg film-coated tablets EU/1/20/1480/003 EU/1/20/1480/004 **Further information:** Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UB8 1QS, United Kingdom 00800 7878 1345 medicalinfo@glpg.com Jyseleca® is a trademark. **Date of Preparation:** January 2022 UK-RA-FIL-202201-00019

▽ Additional monitoring required

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References: 1. JYSELECA SPC. Available at: www.medicines.org.uk. Last accessed: June 2022. **2.** Angelini J, *et al.* Biomolecules 2020;10(7):E1002. **3.** Banerjee S, *et al.* Drugs 2017;77:521–546. **4.** O'Shea JJ, *et al.* Nat Rev Rheumatol 2013;9(3):173–182. **5.** Traves PG, *et al.* Ann Rheum Dis 2021;0:1–11. **6.** McInnes IB, *et al.* Arthr Res Ther 2019;21:183. **7.** Combe B, *et al.* Ann Rheum Dis 2021;doi:10.1136/annrheumdis-2020-219214. **8.** Genovese MC, *et al.* JAMA 2019;322 (4):315–325. **9.** Westhovens R, *et al.* Ann Rheum Dis 2021;doi:10.1136/annrheumdis-2020-219213. **10.** Combe B, *et al.* Arthritis Rheumatol 2021;73(suppl 10). https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-filgotinib-treatment-in-an-ongoing-long-term-extension-trial-of-ra-patients-with-inadequate-response-to-mtx-initially-treated-with-filgotinib-or-adalimumab-during-th/. Last accessed: June 2022. **11.** Buch MH, *et al.* Arthritis Rheumatol 2021;73 (suppl 10). https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-ongoing-filgotinib-ra-long-term-extension-trial-of-biologic-dmard-inadequate-responders-initially-on-filgotinib-or-placebo-in-a-phase-3-trial/. Last accessed: June 2022. **12.** Winthrop K, *et al.* Arthritis Rheumatol 2021;73(suppl 10). Available at: https://acrabstracts.org/abstract/integrated-safety-analysis-update-for-filgotinib-in-patients-with-moderately-to-severely-active-rheumatoid-arthritis-receiving-treatment-over-a-median-of-2-2-years/. Last accessed: June 2022.

Galápagos

June 2022 GB-RA-JY-202205-00033