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Systematic Review and Meta-Analysis

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Clinical science

A meta-analysis and systematic review of the use of transition tools for patients transitioning from paediatric to adult rheumatology services

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Abstract

Objectives: Transitioning from paediatric to adult care can be challenging, but transition tools are designed to increase successful rates of transfer. We aimed to conduct a meta-analysis and systematic review of the use of transition tools in the transfer of care from paediatric to adult services for rheumatology patients.

Methods: An extensive literature search was conducted using MEDLINE, PubMed and Embase. A total of 12 papers were included in the systematic review and 8 in the meta-analysis looking at the use of transition tools in successful follow-up in adult clinics.

Results: The meta-analysis showed 86.6% (95% CI 53.3, 80.6) of patients who used a transition tool attended an adult outpatient clinic within 1 year of their last paediatric appointment, compared with 67.7% (95% CI 56.7, 99.7) of patients who successfully transferred without a transition tool.

Conclusions: The systematic review demonstrated several unique transition tools with local success, but no dominant method. This article demonstrated a general positive influence of transition tools on successful transfer, but more research is needed to strengthen the association.

Lay Summary

What does this mean for patients?

Patients with a rheumatology condition (such as juvenile idiopathic arthritis) that is diagnosed during childhood often need long-term care. There can be challenges when patients move from paediatric to adult rheumatology services after they turn 18 and patients may disengage from services. We looked at whether using interventions designed to support transition (known as transition tools) increases the likelihood that patients continue their follow-up in an adult rheumatology clinic. Examples of transition tools include having a joint clinic with paediatric and adult rheumatologists, having a transition pathway or having a transition coordinator. Having conducted a search for relevant research, we found eight studies that examined the impact of transition tools in rheumatology. The results showed that 86.6% of patients who used a transition tool attended an adult outpatient clinic within 1 year of their last paediatric appointment, compared with 67.7% of patients who attended an adult rheumatology clinic without a transition tool. However, at present, there are not enough studies to make these results statistically significant. In conclusion, more research is needed regarding the use of transition tools in rheumatology.

Keywords: transition, transition tools, juvenile idiopathic arthritis, systemic lupus erythematosus, paediatric

Key messages

- Transition from paediatric to adult care in rheumatology can be challenging.
- Transition tools are likely to improve the transition experience into adult care.
- More research is needed to find which transition tool is best.

Introduction

Rheumatological diseases diagnosed in childhood often necessitate a transition of care from paediatric to adult services. Previous research has highlighted the challenges of transition, especially high rates of loss to follow-up, poorer long-term health outcomes and increased risk of mental illness [1]. Several hypotheses have been cited for this including: follow-up care is not being seen as a priority for adolescents and a lack of training and knowledge to provide adolescent-centred care [2].

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In rheumatology, a transition tool can be defined as: 'Any method designed to improve the transfer of patients from Paediatric Rheumatology Services to Adult Rheumatology Services' [3]. Transition tools can take many forms, including transition coordinators, joint paediatric–adult clinics and the use of transition pathways.

A variety of transition tools have been used and no single transition tool has become the dominant method in rheumatology [4]. In 2016, the National Institute for Health and Care Excellence published guidelines recommending that formal transition tools should be implemented to improve patient experience and outcomes of transition [5]. A previous systematic review of transition for patients with JIA was conducted in 2016 [6]. The results of this showed some benefit around the use of transition tools but concluded that more research was needed.

This study seeks to provide an updated review of both JIA and CTDs, systematically reviewing different transition tools and performing a meta-analysis on whether the use of transition tools affect levels of attendance to adult rheumatology services following paediatric rheumatology service discharge. It is hypothesized that utilising a transition tool increases the likelihood of successful transfer to adult services.

Methods

The study protocol was registered on PROSPERO (CRD42020178112). The study question is: 'Does the use of a formal transition tool improve the transfer of care for patients transferring from paediatric to adult rheumatology clinics?'.

The population included in this systematic review were adults diagnosed with an inflammatory rheumatologic condition in childhood who had completed the transition out of paediatric rheumatology care. The intervention was any specific and named transition tool designed to aid with the transfer from paediatric to adult rheumatology services. The comparator group was patients transitioning out of paediatric rheumatology services without the use of a specific transition tool. The primary outcome was the proportion of patients with a diagnosed rheumatological condition who successfully attended an adult rheumatology clinic within 1 year of their last paediatric appointment and after their 18th birthday (post-transition), which was presented as a meta-analysis. Secondary outcomes included any quantitative post-transition measures of the transition process from paediatric to adult rheumatology settings. Inclusion criteria were studies of paediatric-onset inflammatory rheumatologic disease published in English and reporting quantitative patient outcomes and/or clinic attendance post-transition in an adult rheumatology clinic setting. Exclusion criteria were: qualitative studies, case reports, scoping reviews, previous systematic reviews and conference abstracts, studies where no quantitative outcome measures reported and publications that were unavailable in full text.

Publications were identified by the academic databases MEDLINE (in-process and non-indexed citations) and OVID MEDLINE 1946 to present (OVID), Web of Science, PubMed and EMBASE and a review of the references from these identified studies. The search strategy, including key words and mesh terms was piloted in MEDLINE (Supplementary Data S1, available at *Rheumatology Advances in Practice* online). This elicited relevant results and other databases were searched without any amendments. Search results were extracted into Endnote 10 (Clarivate, London, UK) and duplicates were removed. Articles that met the initial search criteria underwent a title and abstract screening independently by two researchers, with disagreements discussed to ensure consensus. If there were multiple longitudinal articles from the same study, the most recent article was included. Full-text screening was carried out on all papers identified from title and abstract screening as potentially meeting the inclusion criteria. This was done by two reviewers independently. The full texts were obtained by online subscriptions or interlibrary loans. The quality of the included articles was independently assessed by two reviewers using a modified version of the Newcastle–Ottawa Scale. Articles were not excluded based on quality, to present the full range of available evidence. The quality scores are presented in Table 1. The data extraction table was piloted, resulting in one category (mean duration from the final paediatric clinic appointment to the first adult clinic) being removed, as it was only rarely reported. All other categories remained unchanged.

Statistical analysis was carried out using Stata (version 16; StataCorp, College Station, TX, USA). A random effects meta-analysis was conducted using Stata (version 16), due to the distribution of true effects. This was presented as a forest plot and heterogeneity was quantified using I^2.

Results

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) diagram (see Fig. 1) shows the selection of 988 articles. A total of 12 articles met the full inclusion criteria and were included in the systematic review; 7 articles reported quantitative follow-up data for patients post-transition and were included in the meta-analysis. The results of one article (Walter *et al.* [16]) reported separate follow-up data for patients with and without transition tool exposure and were split into two datasets. This provided eight datasets for the meta-analysis. Reference list screening did not elicit any additional studies.

Meta-analysis

Seven articles met the inclusion criteria for the meta-analysis and a subgroup analysis compared rates of successful transition between studies that included a formal transition tool and those that did not. One study presented 2 sets of data, so they were included separately. The eight datasets included a total of 876 patients from four countries. Fig. 2 shows the forest plot for the included studies.

The mean proportion of patients who successfully transferred was 67.74% (95% CI 53.3, 80.6) without a transition tool and 86.03% (95% CI 56.7, 99.7) with a transition tool. There was no statistically significant difference between the proportion who successfully transferred with or without a transition tool, as the confidence intervals (CIs) were overlapping. However, there was a trend that suggested a higher likelihood of successful transition when using a transition tool.

The heterogeneity ($I^2 = 0.94$) of the studies was high, as the term 'transition tool' was broad and encompassed many different interventions. Due to the small number of studies in the meta-analysis, a funnel plot was not completed.

Table 1. Included studies

Study name	Author	Meta-analysis	Publication year	Country	Transition tool; name	Diseases included	Included patients, *n*	Quality assessment	Female, %	Follow-up
Transition of care and health-related outcomes in pediatric-onset systemic lupus erythematosus	Felsenstein *et al.* [7]	N	2015	USA	No	CTD	41	1/7		Retrospective cohort
High rates of unsuccessful transfer to adult care among young adults with juvenile idiopathic arthritis	Hazel *et al.* [8]	Y	2010	Canada	No	JIA	100	0/7	68	Retrospective cohort
The challenges of transferring chronic illness patients to adult care: reflections from pediatric and adult rheumatology at a US academic center	Hersh *et al.* [9]	Y	2009	USA	No	Both	31	1/7	74	Retrospective cohort
The clinical impact of a brief transition programme for young people with juvenile idiopathic arthritis: results of the DON'T RETARD project	Hilderson *et al.* [4]	N	2016	Belgium	Yes; DON'T RETARD	JIA	Total 73	6/7	76	Prospective quasi experimental cohort
Analysis of health care claims during the peri-transfer stage of transition from pediatric to adult care among juvenile idiopathic arthritis patients	Mannion *et al.* [10]	Y	2016	USA	No	JIA	58	1/7	79	Retrospective cohort
Transition to adult rheumatology care is necessary to maintain DMARD therapy in young people with juvenile idiopathic arthritis	Ramos *et al.* [11]	Y	2017	Germany	No	JIA	256	4/7	67	Retrospective cohort
Acceptable quality of life and low disease activity achievable among transition phase patients with rheumatic disease	Relas and Kosola [12]	N	2019	Finland	No	JIA	291	5/7	71	Retrospective cohort
Growing up and moving on in rheumatology: development and preliminary evaluation of a transitional care programme for a multicentre cohort of adolescents with juvenile idiopathic arthritis	McDonagh *et al.* [13]	N	2006	UK	Yes; Growing Up and Moving On	JIA	110/93	7/7		Retrospective cohort
Disease activity and transition outcomes in a childhood-onset systemic lupus erythematosus cohort	Son *et al.* [14]	N	2016	USA	No	CTD	50	2/7	90	Retrospective cohort
Evaluation of a rheumatology transition clinic	Stringer *et al.* [15]	Y	2015	Canada	Yes; Paediatric Rheumatology Transition Clinic, Halifax	Both	51	2/7	78	Retrospective Cohort
Successful implementation of a clinical transition pathway for adolescents with juvenile-onset rheumatic and musculoskeletal diseases	Walter *et al.* [16]	Y	2018	Netherlands	Yes; Individual Transition Plan	Both	154	3/7	64	Retrospective cohort
Patterns of health care utilization and medication adherence among youth with systemic lupus erythematosus during transfer from pediatric to adult care	Chang *et al.* [17]	Y	2020	USA	No	CTD	184	2/7		Retrospective cohort

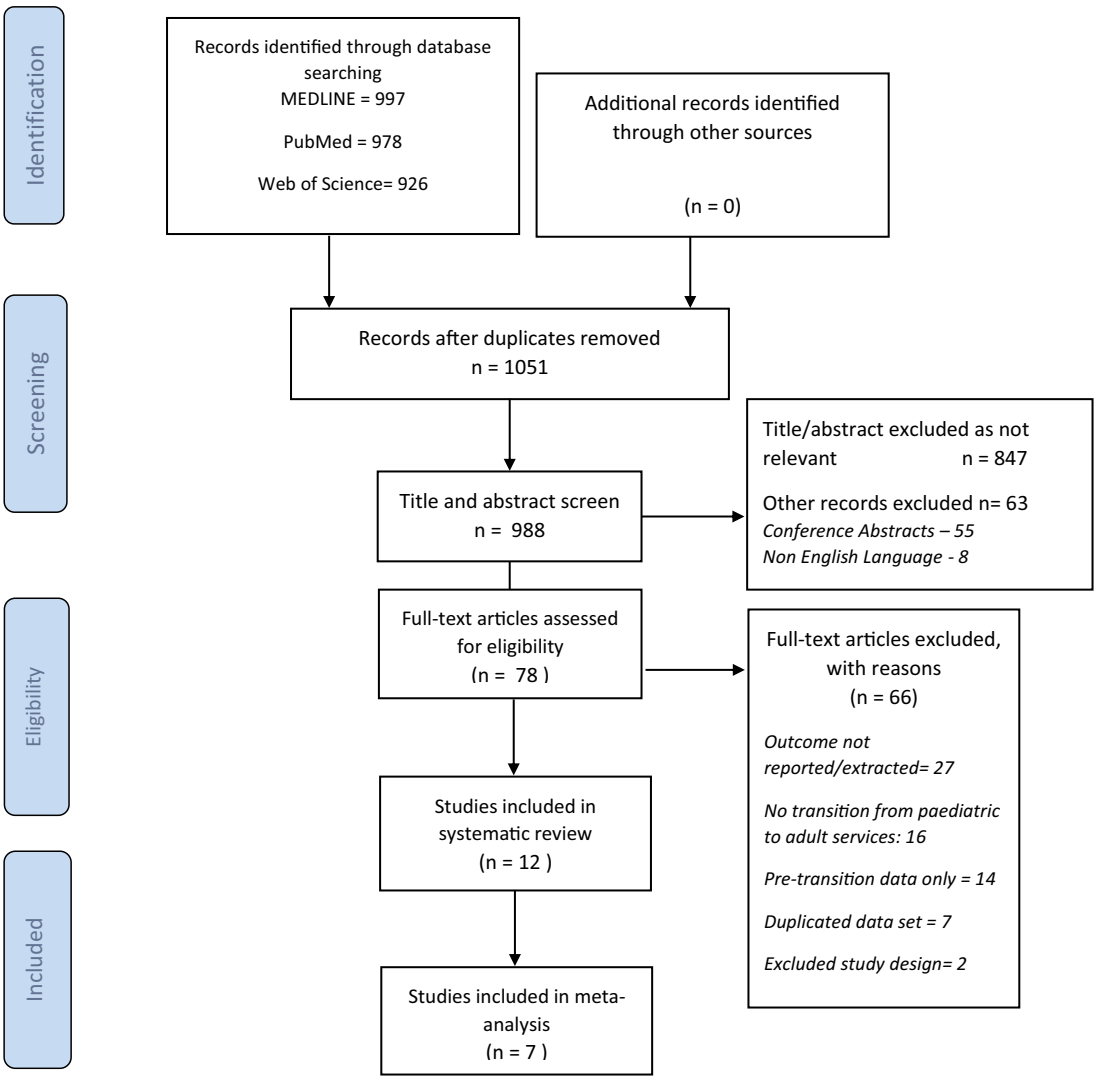

Figure 1. PRISMA flow diagram for study screening and selection for systematic review and meta-analysis

Systematic review—problems with transition

The transition process from paediatric to adult care has consistently been shown to be a challenging time for patients [18]. Quantitatively, this has been demonstrated in a variety of ways: Hersh *et al.* [9] and Chang *et al.* [17] showed an increase in disease activity during the transition period. Disease activity was measured using the 28-joint DAS score in both articles, so was directly comparable. Hersh *et al.* [9] showed an increase in inflammatory markers during the transition period and hypothesized that this increase in disease activity was due to interruptions in care and a loss of continuity. Hilderson *et al.* [4] demonstrated that a cohort of patients followed up with regular outpatient appointments had lower disease activity than a group that had irregular follow-up care. This need for continuity of care is an argument used by Relas and Kosola [12] and Hilderson *et al.* [4] for the implementation of formal transition tools.

Mannion *et al.* [10] reported that the use of emergency medical care increased during the transition period. Nordal *et al.* [19] reported a similar increase associated with poor disease control. Felsenstein *et al.* [7] found an increase in acute medical care usage during the transition period, with lower follow-up rates in planned outpatient clinics being associated with patients accessing emergency healthcare on a regular basis. They concluded that emergency healthcare usage demonstrated a failure of the transition process.

Shaw *et al.* [2] demonstrated high rates of mental health issues among transitioning patients. However, there are confounding factors, as patients with chronic physical health conditions have higher rates of mental illness [20] and the transition age group has had the greatest increase in diagnosed mental illness over the last 10 years [21]. Nevertheless, Shaw *et al.* [2] highlighted that the levels of mental illness in transitioning patients is higher than expected levels, which is supported by other authors [16, 22]. Shaw *et al.* [2] suggested that a smooth transition process would have a positive impact on mental well-being.

Use of transition tools

Transition tools were introduced with the aim of improving the transition process and reducing the challenges described above. Four unique transition tools were described in the included studies. While they all included a formal transition pathway,

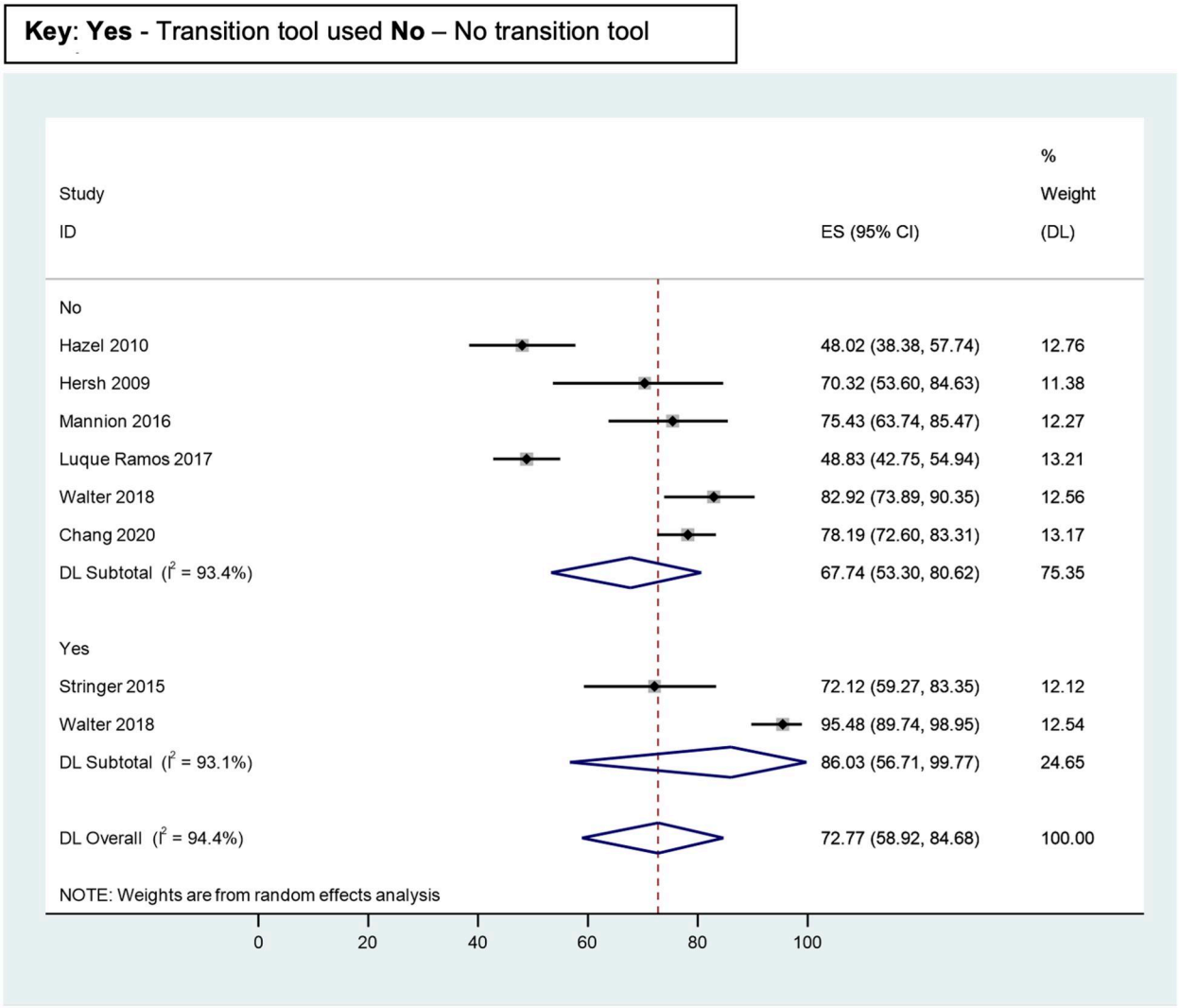

Figure 2. Forest plot of the proportion of patients who transitioned successfully into adult rheumatology care

each transition tool was a distinct entity, which made direct comparison challenging, and the outcome measures were diverse. The specific transition methods used are highlighted in Table 1. The only directly comparable outcome measurement was successful retention of patients into adult follow-up care.

McDonagh *et al.* [13] conducted a review of the Growing Up and Moving On program, first developed in Birmingham, UK. This was the only program reviewed that has been used in multiple centres. The Growing Up and Moving On program included a transition pathway and involved a transition coordinator, preparatory visits to adult rheumatology centres and development workshops to promote independent care. The program was evidence based, with qualitative studies using patient and caregiver focus groups utilized to determine specific interventions. McDonagh *et al.* [13] demonstrated that using the Growing Up and Moving On program resulted in improvements in patient satisfaction and adolescent readiness for transition and met parental needs. They concluded that the Growing Up and Moving On program effectively reduced the barriers to transition.

Hilderson *et al.* [4] reviewed the DON'T RETARD transition tool in The Netherlands. This has many similarities with the Growing Up and Moving On program, as both utilise a transition pathway, although the Growing Up and Moving On program is designed as a brief intervention using a transition coordinator and education sessions. Hilderson *et al.* [4] demonstrated an increase in patient satisfaction, improved physical health and better psychosocial outcomes in a longitudinal pre- and post-intervention evaluation study. While this was a single-centre study, the findings support the McDonagh *et al.* [13] conclusions that a transition pathway can improve the transfer process.

Walter *et al.* [16] conducted a cross-sectional observational study with two cohorts of patients, one cohort with and one without a transition tool. Walter *et al.* [16] demonstrated a statistically significantly higher proportion of patients successfully transferred using the transition pathway. Patient satisfaction scores with the transition process were higher in the transition tool cohort. There are weaknesses of this study, including the fact that the two cohorts were recruited at different time points and may not be directly comparable. However, the conclusions of this study are concordant with other studies, suggesting that transition pathways are successful at improving the transition process.

Discussion

This project was the first meta-analysis examining the proportion of patients who successfully transferred from a paediatric to an adult rheumatology setting and the first systematic review including patients with juvenile-onset CTDs. A previous systematic review from 2016 [23] was a scoping review of transition tools for JIA patients and had limited publication critiques. All articles discussed in that review were included in this article. A recent systematic review of pre-transition outcomes was published by McDonagh and Farre [22], but did not contain data related to post-transition outcomes. Due to the small number of studies, it was not possible to categorize outcome into rheumatological disease subgroups.

The term 'transition tool' is broad, encompassing several different transition methods, reflecting high heterogeneity between studies. The transition methods used in the meta-analysis studies included a joint paediatric/adult clinic [15] and a transition pathway with individual transition plans [16]. With only two 'active intervention' studies, it was not possible to undertake a subgroup analysis of different transition methods. Many studies reviewed within the systematic review analysed the benefits of a transition tool, however, they were not included in the meta-analysis, as they did not have outcome data post-transition.

The benefits of a transition tool on the successful transfer of patients have also been shown in other specialties. In psychiatry, a transition pathway [24] led to an increase in successful follow-up in adult care, and in patients with type 1 diabetes, a joint paediatric/adult clinic increased patients transferring from paediatric to adult care [25], with improved continuity of care and lower patient anxiety.

Due to the small number of studies included, it was not possible to conclusively determine whether transition tools improve transfer to adult care, but the results appear to be generally concordant. However, more research is needed to prove this hypothesis.

The Ready Steady Go checklist [26] of a young person's readiness for transition into adult care, published by Southampton Children's Hospital, Southampton, UK is now widely used across multiple medical specialities in the UK. No articles were found regarding the utility of this checklist in a rheumatology setting. Connett and Nagra [26] highlighted the importance of having a clear transition policy that is communicated to patients and their families at an early stage. The Ready Steady Go checklist empowers patients to become autonomous in their care and agree on shared goals. This concept was also central in both the Growing Up and Moving On program and the DON'T RETARD pathways.

Due to the small number and high heterogeneity of studies, it was not possible to reach definitive conclusions around the benefits of individual elements of transition pathways/tools. However, the consensus of the evidence demonstrates that a specific transition pathway that is clearly communicated to patients and families is vital in managing the transition process. However, creating an individualized plan is important, as it recognizes the diversity of adolescent development and maturity. All transition programs reviewed have an early entry point, often 7 or 8 years prior to the actual transfer date. McDonagh and Farre [22] cited the importance of discussing transition early in managing expectations and future planning. However, transition pathways commencing in early adolescence need to be developmentally appropriate and will have a different approach to transition tools commenced at a later age.

The use of a 'transition coordinator' increased patient satisfaction and provided a contact point. However, the role and responsibilities of the transition coordinator varied significantly between different transition pathways, so it was not possible to make definitive conclusions around their effectiveness.

The evidence for the use of written literature in transition is limited. Ramos *et al.* [11] showed that there was limited engagement by adolescent patients with printed information. Campbell *et al.* [27] demonstrated that patient knowledge about their condition was higher when they attended an audio-visual workshop compared with the use of printed media. This has been supported with evidence from other specialties and pedagogical research around adolescent learning [28].

Although joint adult and paediatric clinics are widely used in transition, evidence to support them is limited. Challenges of logistical barriers (adult clinics are often held in a different location and often by different care providers than paediatric clinics) and clinician workload were cited as reasons why this method was not formally used in transition pathways. Nevertheless, the evidence available [27] suggests that patients found the opportunity to meet their new adult team beneficial.

Both Growing Up and Moving On and DON'T RETARD had development workshops that aimed to increase patient knowledge around disease management. Qualitative evidence [4] indicated high levels of patient and care satisfaction with the workshops, but their subsequent impact on transition into adult rheumatology services is yet to be determined. Development workshops have been used successfully in diabetes transitional care [25], although the focus was around practical education for insulin injections and diabetes control.

Strengths and limitations

This study adhered to the PRISMA guidelines throughout the literature search and review of articles (Supplementary Data S2, available at *Rheumatology Advances in Practice* online). The protocol was accepted for publication on the PROSPERO database.

There was a comprehensive literature review with broad search criteria, initially eliciting 988 articles. Four databases were searched, with a high number of duplicated papers found, demonstrating saturation of the search strategy. Review of the reference lists of included articles did not identify any additional studies.

All articles were independently reviewed by a minimum of two reviewers using an online tool, which allowed for simultaneous yet independent assessment. The meta-analysis was carried out using the latest software and using a random effects model.

This review is limited by the inclusion of only a small number of articles despite a comprehensive literature search. The selected studies had high heterogeneity and diversity in outcome measures, with many having low overall quality assessment scores (mean score 3.7/7) and potential confounding factors, including age, gender, developmental status and other medical comorbidities, and the majority of articles did not account for these confounding factors.

No randomized controlled trials or case–control studies were identified. All articles evaluating post-transition outcomes were conducted in a single centre, with a small cohort of patients. There were no large, multicentre studies, limiting assessment around the generalizability of these studies.

The search strategy was restricted to English-language articles only. Although only one non-English-language article was excluded (at the title and abstract stage), the search strategy was written in English and may not have found relevant articles written in another language. However, articles were included from around the world.

A challenge of transition is the fact that transfer from paediatric to adult care often necessitates a change in hospital location and often care providers. This makes research logistically difficult, which was reflected in the lack of studies following patients through the entire transition process. Many studies presented pre-transition data, but few articles report post-transition outcomes. This made evaluating the entire transition process challenging.

Implications for clinical practice and suggestions for further research

The trend of the data appears to suggest that the use of transition tools improves patient outcomes in the transfer process from paediatric to adult care. These findings could improve patient outcomes during the transition phase by encouraging healthcare providers to implement a formal transition plan.

Anecdotal evidence appears to suggest that many centres have a transition tool in place. However, the limited amount of published research in this area has restricted the opportunity to draw specific conclusions around the effectiveness of transition tools. A widely used transition tool was the Ready, Steady, Go pathway, which has not been formally evaluated in a rheumatological setting. Further research could focus on evaluating existing transition pathways to formally establish their benefits.

More research could be conducted around which specific elements of transition pathways are most effective at improving the transfer process. This could take the form of a higher-level study design, such as a randomized controlled trial comparing different transition elements (e.g. a joint adult/paediatric clinic *vs* a transition coordinator). Many transition research projects conclude prior to transition, limiting available data on actual transition success. Future research aiming to extend follow-up through transition and into adult care would be logistically challenging but would allow for accurate evaluation of current transition tools.

Conclusion

This systematic review and meta-analysis demonstrated that the use of a transition tool increases the proportion of patients who successfully transfer from a paediatric to an adult rheumatology setting. The meta-analysis found a higher proportion of patients successfully transitioning to adult care with a transition tool than without. However, due to the small number of studies, the CIs were wide. Due to the limited evidence available and wide variation between studies, further research is vital to demonstrate the effectiveness of transition tools.

Supplementary material

Supplementary material is available at *Rheumatology Advances in Practice* online.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions

K.G. was the lead author and reviewer and conducted the search, selection and analysis of papers. F.P. and J.P. were co-supervisors and supported with review and selection of papers and reviewed the paper.

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Systematic Review and Meta-Analysis

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Adapted from Cosentyx® (secukinumab) SmPC.[4,5]

*For adult patients with PsA and concomitant moderate to severe PsO, the recommended dose of Cosentyx is 300 mg with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by **monthly maintenance dosing**. Based on clinical response, a maintenance dose of 300 mg **Q2W** may provide additional benefit for patients with a body weight of **90 kg or higher**.[4,5]

Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adult patients (alone or in combination with methotrexate) when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic therapy; active enthesitis-related arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.[4,5]

PsA, psoriatic arthritis; PsO, plaque psoriasis; Q2W, every 2 weeks.

References: 1. Warren RB, et al. *J Invest Dermatol* 2015;135:2632–2640; **2.** Warren RB, et al. *Br J Dermatol* 2019;180(5):1069–1076; **3.** Office for Health Improvement and Disparities. Obesity profile: short statistical commentary May 2024. Available at: https://www.gov.uk/government/statistics/update-to-the-obesity-profile-on-fingertips/obesity-profile-short-statistical-commentary-may-2024 [Accessed August 2024]; **4.** Cosentyx® (secukinumab) GB Summary of Product Characteristics; **5.** Cosentyx® (secukinumab) NI Summary of Product Characteristics.

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Cosentyx® (secukinumab) Great Britain Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 75 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 75 mg dose is given as one injection of 75 mg. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 75mg and 150 mg pre-filled syringe and 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. *Fertility:* Effect on human fertility not evaluated. **Adverse Reactions**: *Very Common (≥1/10):* Upper respiratory tract infection. *Common (≥1/100 to <1/10):* Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). *Neutropenia:* Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity:* Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** PLGB 00101/1205 – 75 mg pre-filled syringe x 1 - £304.70; PLGB 00101/1029 - 150 mg pre-filled pen x2 £1,218.78; PLGB 00101/1030 - 150 mg pre-filled syringe x2 £1,218.78; PLGB 00101/1198 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** June 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report.

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com

Cosentyx® (secukinumab) Northern Ireland Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg monthly. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab than placebo in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. *Fertility:* Effect on human fertility not evaluated. **Adverse Reactions**: *Very Common* (≥1/10): Upper respiratory tract infection. *Common* (≥1/100 to <1/10): Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). *Neutropenia:* Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity*: Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/010 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** May 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com