

Impact of clinical and patient pathway changes on paediatric research during the national COVID-19 response

In March 2020, in response to the COVID-19 pandemic, national strategies were implemented across Scotland to contain the spread of the virus, including lockdown measures, travel restrictions and the closure of schools and non-essential services. The National Institute for Health Research (NIHR) and the devolved nations prioritised nationally sponsored COVID-19 research and front-line care.¹ As a result, 78% of paediatric studies in Scotland were suspended.

In August 2020 after the first COVID-19 wave, the RESTART programme was initiated across health boards to reopen commercial and non-commercial research studies. By March 2021, most paediatric studies were categorised as open to recruitment but without the expected resurgence of patient recruitment. We therefore surveyed the principal investigators (PI) about their opinions on factors, specifically those related to the national COVID-19 strategies, that were affecting recruitment to their paediatric studies.

A survey of 11 questions, designed using the SNAP Survey software and hosted on a secure University of Aberdeen server, was sent to the 105 PIs listed in the national database (Scottish Research Management Database) under the paediatric portfolio. The survey was open from 16 March to 16 April 2021.

The 72 responses received were proportionate to the National Health Service-National Research Services Children's Research Network portfolio categorisation by health board, specialty, study type and whether studies are embedded in clinical care (table 1).

The survey highlighted factors within the clinical environment that were considered to have a negative impact on recruitment and follow-up visits (table 2):

- 1. Availability** Reduced availability of staff was reported most frequently, exacerbated by staff redeployment to COVID-19-related adult research and vaccine studies.
- 2. Frequency** Factors that collectively reduced the frequency of interactions with potential study participants and

Table 1 Breakdown of 72 responses to survey of paediatric principal investigators in Scotland

Breakdown of responses	
Health board	NHS Greater Glasgow and Clyde 28, NHS Lothian 18, NHS Grampian 12, NHS Tayside 10, NHS Ayrshire and Arran 2, NHS Lanarkshire 1, NHS Fife 1
Specialty	Neurology 17 (24%), Respiratory 13 (18%), Gastroenterology 6 (8%), Neonatology 4 (6%), Anaesthesia 4 (6%), Surgery 4 (6%), Rheumatology 4 (6%), Infectious diseases 2 (4%), Intensive medicine 3 (4%), Dermatology 2 (3%), Endocrinology 2 (3%), Other 4 (6%)
Study type	50% Clinical Trials of an Investigational Medicinal Product (CTIMPs), 24% interventional trials not involving an IMP (non-CTIMP), 20% observational studies, 6% registries 63% considered their study to be embedded in clinical care.

NHS, National Health Service.

Table 2 The total number and percentage of Yes responses to 'Has recruitment been affected by changes to the clinical pathway in your specialty?' and 'Have follow-up visits been affected by changes to the clinical pathway in your specialty?'

Categories	Has recruitment been affected by changes to the clinical pathway in your specialty? Please select all that apply.	Have follow-up visits been affected by changes to the clinical pathway in your specialty? Please select all that apply.
Patients not attending routine clinics	14 (22.6%)	16 (30.2%)
Patients not attending face-to-face appointments	16 (25.8%)	21 (39.6%)
Patients/parents not keen to attend face-to-face appointments	11 (17.7%)	11 (20.8%)
Elective procedures suspended	13 (21.0%)	7 (13.2%)
Supportive procedures not available—for example, radiology, cardiology, ophthalmology	4 (6.5%)	3 (5.7%)
Staff to support research not available due to staff redeployment or shortages	21 (33.9%)	20 (37.7%)
You have less time due to clinical pressure	15 (24.2%)	7 (13.2%)
Less opportunity to recruit patients due to social distancing requirements	17 (27.4%)	8 (15.1%)

their families, including reduced clinics, travel restrictions between health board areas, reduced willingness to invite patients to hospital and postponement of elective procedures.

- 3. Quality** Factors that impacted on the quality of interactions with patients and families, including the replacement of face-to-face visits by telephone or video calls, socially distanced visits with less family members present and wearing of face masks.

Furthermore, changes in the incidence of some conditions were considered to have affected recruitment to specific studies including a significant reduction in seasonal respiratory infections, and in fractures presenting to emergency departments, explained by lockdown and suspension of sports and school activities.

In conclusion, the national and local NHS strategies implemented to reduce the spread of COVID-19 have collectively had a significantly negative impact on recruitment of children to research studies in Scotland. Through consultation

with the NIHR Clinical Research Network: Children and Young People National Specialty Group, these findings reflect the issues faced in paediatric research in England, Northern Ireland and Wales.

We envisage that the increased frequency and quality of clinical visits in conjunction with the NIHR National Managed Recovery process should lead to paediatric research activity returning to prepandemic levels. We believe that the reinstatement of clinical services and unrestricted movement of research staff within the clinical areas will particularly benefit studies with opportunistic patient recruitment.

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- 1 DHSC issues guidance on the impact of COVID-19 on research funded or supported by NIHR. Available: <https://www.nihr.ac.uk/news/dhsc-issues-guidance-on-the-impact-of-covid-19-on-research-funded-or-supported-by-nihr/24469> [Accessed 16 Mar 2020].