

Report by Acting Chief Executive – monthly update: September 2020

Authors: Rebecca Brown and Stephen Ward

Sponsor: Rebecca Brown

Trust Board paper E

Purpose of report:

This paper is for:	Description	Select (X)
Decision	To formally receive a report and approve its recommendations OR a particular course of action	
Discussion	To discuss, in depth, a report noting its implications without formally approving a recommendation or action	X
Assurance	To assure the Board that systems and processes are in place, or to advise a gap along with treatment plan	
Noting	For noting without the need for discussion	

Previous consideration:

Meeting	Date	Please clarify the purpose of the paper to that meeting using the categories above
CMG Board (specify which CMG)	N/A	
Executive Board	N/A	
Trust Board Committee	N/A	
Trust Board	N/A	

Executive Summary

Context

The Acting Chief Executive's monthly update report to the Trust Board for September 2020 is attached.

Questions

Does the Trust Board have any questions or comments about our performance and plans on the matters set out in the report?

Conclusion

The Trust Board is asked to consider and comment upon the issues identified in the report.

Input Sought

We would welcome the Board's input regarding the content of this month's report to the Board.

For Reference:

This report relates to the following UHL quality and supporting priorities:

1. Quality priorities

Safe, surgery and procedures	[Yes]
Safely and timely discharge	[Yes]
Improved Cancer pathways	[Yes]
Streamlined emergency care	[Yes]
Better care pathways	[Yes]
Ward accreditation	[Yes]

2. Supporting priorities:

People strategy implementation	[Yes]
Estate investment and reconfiguration	[Yes]
e-Hospital	[Yes]
More embedded research	[Yes]
Better corporate services	[Yes]
Quality strategy development	[Yes]

3. Equality Impact Assessment and Patient and Public Involvement considerations:

- What was the outcome of your Equality Impact Assessment (EIA)? N/A
- Briefly describe the Patient and Public Involvement (PPI) activities undertaken in relation to this report, or confirm that none were required – None Required.
- How did the outcome of the EIA influence your Patient and Public Involvement ? N/A
- If an EIA was not carried out, what was the rationale for this decision? On the basis that this is a monthly update report.

4. Risk and Assurance**Risk Reference:**

Does this paper reference a risk event?	Select (X)	Risk Description:
Strategic: Does this link to a Principal Risk on the BAF?	X	ALL
Organisational: Does this link to an Operational/Corporate Risk on Datix Register	X	There are several risks which feature on the organisational risk register relating to matters covered in this paper.
New Risk identified in paper: What type and description ?	N/A	N/A
None		

5. Scheduled date for the **next paper** on this topic: October 2020 Trust Board
6. Executive Summaries should not exceed **5 sides** [My paper does comply]

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: TRUST BOARD
DATE: 3 SEPTEMBER 2020
REPORT BY: ACTING CHIEF EXECUTIVE
SUBJECT: MONTHLY UPDATE REPORT – SEPTEMBER 2020

1. Introduction

1.1 My report this month is confined to a number of issues which I think it important to highlight to the Trust Board.

2. UHL response to COVID-19

Current Position

2.1 I will report orally at the Trust Board on the current position.

3. Quality and Performance Dashboard – July 2020

3.1 The Quality and Performance Dashboard for July 2020 is appended to this report at **appendix 1**.

3.2 The Dashboard aims to ensure that Board members are able to see at a glance how we are performing against a range of key measures.

3.3 The more comprehensive monthly Quality and Performance report has been reviewed as part of the August 2020 People, Process and Performance Committee and Quality and Outcomes Committee assurance calls. The [month 4 quality and performance report](#) is published on the Trust's website.

4. Health Inequalities

4.1 My report to the 6 August 2020 Trust Board included the 31 July 2020 letter from NHS England and NHS Improvement, setting out the next (3rd) phase of the NHS response to COVID-19. That letter included a requirement (by September 2020) for Trusts to identify an Executive Board member with lead responsibility for tackling health inequalities: within UHL that will be the post of Director of Strategy and Communications. Sarah Prema is the designated LLR system lead director for tackling health inequalities.

5. Research and Innovation – COVID-19 Clinical Research

5.1 The Trust Board currently receives quarterly updates on UHL Research and Innovation (R&I) developments. I am pleased to attach a copy of the latest update from the Trust's Director of Research and Development at **appendix 2**, which

outlines UHL's excellent performance in supporting national COVID-19 priority research studies. This update was presented to UHL's Executive Strategy Board on 4 August 2020.

COVID-19 impact on research and innovation

- 5.2 As outlined in appendix 2, in response to the COVID-19 pandemic and alongside the changes to clinical service delivery at UHL, much existing clinical research was paused and the clinical research infrastructure pivoted to support national COVID-19 priority studies. Since then 96% of patients with suspected or confirmed COVID-19 have been enrolled into at least 1 study at UHL. Over 50% of these patients were enrolled into an interventional study. The average for hospitals across the country is 13%.
- 5.3 UHL has been the highest recruiter to COVID-19 studies in England and this performance has been mentioned in Cabinet, acknowledged in national briefings by the Secretary of State for Health and discussed at the highest level by the National Institute for Health Research (NIHR). Representatives from UHL have advised nationally on the COVID-19 research response, and senior colleagues from NIHR have attended UHL R&I meetings to observe how we work.

COVID -19 related funding awards

- 5.4 The following major funding awards have been made to Leicester investigators:
- UK Reach – a new £2.1m UK study launched to investigate COVID-19 risks for BAME healthcare staff
 - PHOSP Study – £8.4m Post-Hospitalisation COVID-19 Study (PHOSP-COVID), led by the NIHR Leicester Biomedical Research Centre
 - NIHR Patient Recruitment Centre (PRC) - £1.5m awarded to establish PRC at LGH based in the Leicester Diabetes Centre to deliver late-phase commercial research studies. This is 1 of only 5 awarded in England, and the PRC will support COVID-19 vaccine studies.

6. Winter Pressures

- 6.1 The Government has announced £2m of capital funding for our Emergency Department. This will enable us to increase our capacity as part of our winter plans, supporting us to continue to treat COVID and non-COVID patients, and provide the space required for safe distancing on site. The monies will be used to increase the provision of same day emergency care and improve patient flow in the hospital to help UHL to respond to winter pressures and the risk from further outbreaks of coronavirus. The projects will be completed by the start of next year so we benefit from the upgrades during the peak of winter.

7. 'Drop of Compassion' Support for the UHL Children's Hospital Appeal

7.1 I am immensely grateful to the Leicester-based Muslim charity Drop of Compassion, who have donated £250,000 to UHL for our Children's Hospital Appeal. I was able to meet with some of their fundraisers who have worked tirelessly to raise money for this very special project. In a key milestone, our Children's Hospital Appeal has now reached the £5m mark on its way to the £7.5m phase 1 target to support the new dedicated Children's Hospital at the Leicester Royal Infirmary.

8. Microbiology UKAS Accreditation

8.1 I am delighted to confirm that the Trust's Microbiology service have retained their status as an accredited laboratory, having passed their annual UKAS accreditation on 18 August 2020. This is an excellent achievement by the Microbiology team, who will take forward any recommendations to ensure that accreditation is maintained. The assessors complimented the UHL Microbiology team for quality being at the core of the laboratory; this was well received by the team as this is where the Covid-19 testing has been delivered on top of day-to-day business.

9. National NHS People Plan

9.1 It is really exciting that the long awaited NHS People Plan has now landed. This is the biggest People Strategy in the world and is very welcomed in the NHS. It is really putting our people at the heart of how we operate and how we lead to make the NHS the best place to work. Hazel Wyton, Director of People and OD will be presenting our approach and delivery of the People Plan at the November 2020 Trust Board.

10. Conclusion






10.1 The Trust Board is invited to consider and comment upon this report and the attached appendices.




Rebecca Brown
Acting Chief Executive

21 August 2020

Quality and Performance Report Board Summary July 2020

This dashboard uses icons to indicate if a process is showing special cause or common cause variation. It also indicates whether the process is able to meet any stated target. Here is a key to the icons

Icon	Description
	Special cause variation - cause for concern (indicator where high is a concern)
	Special cause variation - cause for concern (indicator where low is a concern)
	Common cause variation
	Special cause variation - improvement (indicator where high is good)
	Special cause variation - improvement (indicator where low is good)

Icon	Description
	The system is expected to consistently fail the target
	The system is expected to consistently pass the target
	The system may achieve or fail the target subject to random variation

These icons are used to indicate statistical variation. We have identified special cause variation based on three rules which are shown below. If none of the rules are present then the metric is showing common cause variation.

- An upwards or downwards trend in performance for seven or more consecutive months.
- Seven or more months above or below the average.
- One month or more outside the control limits .

Green indicates that the metric has passed the monthly or YTD target while **Red** indicates a failure to do so.

The trend shows performance for the most recent 13 months.

Data Quality Assessment – The Data Quality Forum panel is presented with an overview of data collection and processing for each performance indicator in order to gain assurance by best endeavours that it is of suitably high quality. The forum provides scrutiny and challenge on the quality of data presented, via the attributes of (i) Sign off and Validation (ii) Timeliness and Completeness (iii) Audit and Accuracy and (iv) Systems and Data Capture to calculate an assurance rating.

These icons are used to indicate if a target is likely to be achieved next month, has the potential to be achieved or is expected to fail.

Quality and Performance Report Board Summary July 2020

Domain	KPI	Target	May-20	Jun-20	Jul-20	YTD	Assurance	Variation	Trend	Data Quality Assessment	
Safe	Never events	0	0	1	0	2				Jan-20	
	Overdue CAS alerts	0	0	0	0	0				Nov-19	
	% of all adults VTE Risk Assessment on Admission	95%	Data collection paused as part of COVID-19 reducing the burden								Dec-19
	Emergency C-section rate	No Target	21.2%	20.5%	20.2%	19.8%				Feb-20	
	Clostridium Difficile	108	4	4	7	25				Nov-17	
	MRSA Total	0	0	0	0	0				Nov-17	
	E. Coli Bacteraemias Acute	No Target	6	13	12	32				Jun-18	
	MSSA Acute	No Target	1	1	5	8				Nov-17	
	COVID-19 Community Acquired <= 2 days after admission	No Target	62.4%	77.8%	93.5%	78.7%				TBC	
	COVID-19 Hospital-onset, indeterminate, 3-7 days after admission	No Target	11.6%	10.2%	3.2%	8.6%				TBC	
	COVID-19 Hospital-onset, probable, 8-14 days after admission	No Target	16.9%	7.4%	2.2%	7.5%				TBC	
	COVID-19 Hospital-onset, healthcare-acquired, 15 or more days after admission	No Target	9.0%	4.6%	1.1%	5.2%				TBC	
	All falls reported per 1000 bed stays	5.5	5.5	3.8		4.9				Jun-18	
	Rate of Moderate harm and above Falls PSIs with finally approved status per 1,000 bed days	No Target	0.08	0.08		0.09				TBC	

Domain	KPI	Target	May-20	Jun-20	Jul-20	YTD	Assurance	Variation	Trend	Data Quality Assessment	
Caring	Staff Survey Recommend for treatment	No Target	Data collection paused as part of COVID-19 reducing the burden								Aug-17
	Single Sex Breaches	0	Data collection paused as part of COVID-19 reducing the burden								Dec-16
	Inpatient and Daycase F&F Test % Positive	96%	Data collection paused as part of COVID-19 reducing the burden								Jun-17
	A&E F&F Test % Positive	94%	Data collection paused as part of COVID-19 reducing the burden								Jun-17
	Maternity F&F Test % Positive	96%	Data collection paused as part of COVID-19 reducing the burden								Jun-17
	Outpatient F&F Test % Positive	94%	Data collection paused as part of COVID-19 reducing the burden								Jun-17
	Complaints per 1,000 staff (WTE)	No Target	Data collection paused as part of COVID-19 reducing the burden								Jan-20

Domain	KPI	Target	May-20	Jun-20	Jul-20	YTD	Assurance	Variation	Trend	Data Quality Assessment	
Well Led	Staff Survey % Recommend as Place to Work	No Target	Data collection paused as part of COVID-19 reducing the burden								Sep-17
	Turnover Rate	10%	7.8%	7.6%	7.9%	7.9%				Nov-19	
	Sickness Absence	3%	8.8%	6.9%		8.9%				Oct-16	
	% of Staff with Annual Appraisal	95%	83.4%	74.1%	74.4%	74.4%				Dec-16	
	Statutory and Mandatory Training	95%	96%	96%	96%	96%				Feb-20	
	Nursing Vacancies	No Target	10.0%	10.1%		10.1%				Dec-19	

Quality and Performance Report Board Summary July 2020

Domain	KPI	Target	May-20	Jun-20	Jul-20	YTD	Assurance	Variation	Trend	Data Quality Assessment
Effective	Mortality Published SHMI	99	95	95	96	96 (Apr 19 to Mar 20)				Sep-16
	Mortality 12 months HSMR	99	93	93	95	95 (Apr 19 to Mar 20)				Sep-16
	Crude Mortality Rate	No Target	2.3%	1.6%	1.3%	2.1%				Sep-16
	Emergency Readmissions within 30 Days	8.5%	10.2%	9.8%		10.1%	?			Jun-17
	Emergency Readmissions within 48 hours	No Target	1.2%	1.1%		1.2%				Jun-17
	No of #neck of femurs operated on 0-35hrs	72%	32.1%	86.1%	81.9%	70.3%	?			Jul-17
	Stroke - 90% Stay on a Stroke Unit	80%	91.5%	89.3%		87.1%	?			Apr-18
	Stroke TIA Clinic Within 24hrs	60%	63.8%	45.5%	92.1%	69.0%	?			Apr-18

Domain	KPI	Target	May-20	Jun-20	Jul-20	YTD	Assurance	Variation	Trend	Data Quality Assessment	
Responsive	ED 4 hour waits UHL	95%	82.7%	78.2%	79.0%	81.1%	F			Sep-18	
	ED 4 hour waits Acute Footprint	95%	87.5%	84.5%	85.6%	86.6%	F			Aug-17	
	12 hour trolley waits in A&E	0	0	0	0	0	?			Mar-19	
	Ambulance handover >60mins	0.0%	0.5%	0.4%	0.7%	0.6%	F			TBC	
	RTT Incompletes	92%	60.8%	51.5%	44.4%	44.4%	F			Nov-19	
	RTT Waiting 52+ Weeks	0	778	1495	2359	2359	?	H		Nov-19	
	Total Number of Incompletes	66,397 (by year end)	64,959	66,082	67,854	67,854	?	H		Nov-19	
	6 Week Diagnostic Test Waiting Times	1.0%	20.7%	24.4%	32.5%	32.5%	?	H		Nov-19	
	Cancelled Patients not offered <28 Days	0	7	7	8	107	?			Nov-19	
	% Operations Cancelled OTD	1.0%	0.7%	0.5%	0.5%	0.7%	?			Jul-18	
	Delayed Transfers of Care	3.5%	Data collection paused as part of COVID-19 reducing the burden					P			Oct-17
	Long Stay Patients (21+ days)	70	103	122	117	117	F			TBC	
	Inpatient Average LOS	No Target	3.3	3.8	3.6	3.8					TBC
	Emergency Average LOS	No Target	4.5	4.8	4.7	4.8					TBC

Domain	KPI	Target	Apr-20	May-20	Jun-20	YTD	Assurance	Variation	Trend	Data Quality Assessment
Responsive - Cancer	2WW	93%	86.4%	86.9%	92.1%	88.8%	?			Dec-19
	2WW Breast	93%	90.0%	95.5%	96.3%	95.7%	?			Dec-19
	31 Day	96%	94.7%	89.3%	89.7%	91.1%	?			Dec-19
	31 Day Drugs	98%	100%	100%	98.9%	100%	P			Dec-19
	31 Day Sub Surgery	94%	71.9%	83.2%	70.5%	75.9%	?			Dec-19
	31 Day Radiotherapy	94%	57.7%	90.4%	94.4%	81.4%	?			Dec-19
	Cancer 62 Day	85%	64.1%	56.1%	70.6%	64.6%	F			Dec-19
	Cancer 62 Day Consultant Screening	90%	95.7%	25.0%	0.0%	39.0%	?	H		Dec-19

Domain	KPI	Target	May-20	Jun-20	Jul-20	YTD	Assurance	Variation	Trend	Data Quality Assessment
Outpatient Transformation	% DNA rate	No Target	5.7%	5.9%	6.2%	6.2%				Feb-20
	% Virtual clinic appointments	No Target	9.5%	7.6%	7.8%	8.7%		H		Feb-20
	% 7 day turnaround of OP clinic letters	90%	92.5%	94.3%	89.7%	91.7%	?			Feb-20

R&I Update COVID-19 Clinical Research Response

ESB Paper L

Purpose of report:

This paper is for:	Description	Select (X)
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Noting	For noting without the need for discussion	X

In response to the Covid-19 pandemic, and alongside the changes to clinical service delivery at UHL, much existing clinical research was paused and the clinical research infrastructure pivoted to support national COVID-19 priority studies.

Since then 96% of patients with suspected or confirmed COVID-19 have been enrolled into at least one study at UHL. Over 50% of these patients were enrolled into an interventional study. The average for hospitals across the country is 13%.

UHL has been the highest recruiter to Covid 19 studies in England and this performance has been mentioned in Cabinet, acknowledged in national briefings by the Secretary of State for Health and discussed at the highest level by NIHR. Representatives from UHL have advised nationally on Covid research response and senior colleagues from NIHR have attended UHL R&I Meetings to observe how we work.

Some examples of study recruitment are shown in the Table below.

Project Short title	Recruits
ISARIC	1478
REMAP-CAP	26
NHS Check	693
RECOVERY trial	609
RECOVERY - Respiratory Support	17
SIREN	388
SYNAIRGEN	12
PANCOVID	40
Total	3263

New Research Funding and Outputs

Two major new funding awards have been made to Leicester investigators in the last month UK Reach – a new £2.1m UK study launched to investigate COVID-19 risks for BAME healthcare staff

PHOSP Study – £8.4m Post-Hospitalisation COVID-19 Study (PHOSP-COVID), led by the NIHR Leicester Biomedical Research Centre.

NIHR Patient Recruitment Centre - £1.5m awarded to establish PRC at LGH based in the Leicester Diabetes Centre to deliver late-phase commercial research studies. One of only 5 awarded in England. PRC will support Covid-19 vaccine studies.

Leicester Leading

The 2 accompanying papers describe

- Leicester’s national leading work in research PPI/E
- an analysis of Leicester’s research performance that was presented to Leicestershire Academic Health Partners Board in June 2020.

Perceptions of Risk of Attending Hospital during the COVID-19 Pandemic: a UK public opinion survey



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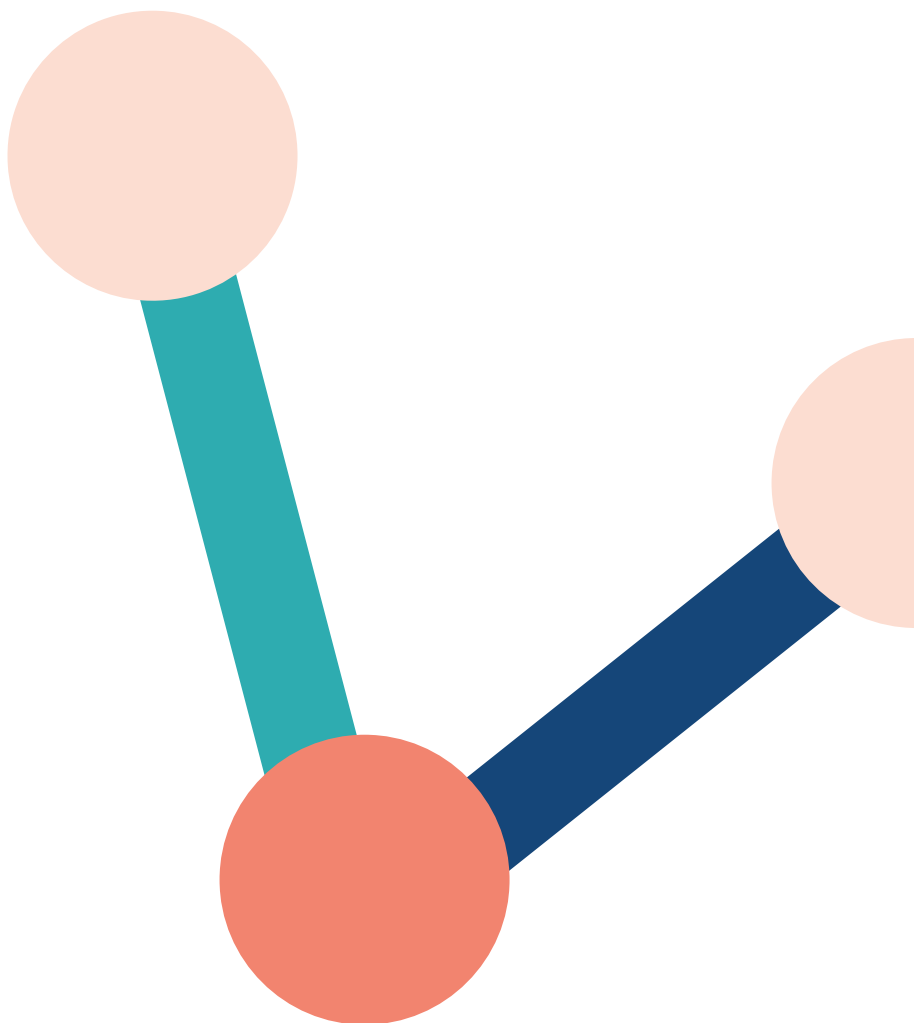
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Abstract

In order to inform clinical and research practice in secondary care in light of the COVID-19 pandemic, an online survey was used to collect public opinions on attending hospitals. The survey link was circulated via the National Institute for Health Research (NIHR) Public Involvement (PPI) Leads network and social media. 402 people completed the survey. Participants age ranged from the 18-85+, with the majority (337 (84%)) aged between 35 to 74 years. There were a higher number of women (77%) compared to men (23%); and were mainly White European (91%) compared to BAME (6%), or other (2%).

Data collection included self-identified risk status due to comorbidity or age, and 100 point Likert-type scales to measures feelings of safety, factors affecting feelings of safety, intention to participate in research, comfort with new ways of working and attitudes to research.

Results for feelings of safety scales indicate two distinct groups; one of respondents who felt quite safe and one of those who did not. Implementation of COVID-19 related safety measures such as social distancing, use of PPE and cleaning were strongly supported by most respondents. There was ambivalence around less certain measures such as regular staff antigen and antibody testing. Respondents were most likely to participate in research related to their own condition, COVID-19 research and vaccine research, but less likely to participate in healthy volunteer research, especially if suffering from a pre-existing comorbidity identified with increased risk or were female. There was general agreement that participants are comfortable with new ways of working, such as remote consultation, though women and BAME respondents were less comfortable. Findings raise concerns for health inequalities already impacting some groups in the pandemic. The role of clinical necessity and personal benefit support the reopening of services in line with clinical necessity. Moderate caution in respect of vaccine research relative to patient-participant research presents a challenge for pending recruitment demands, and would benefit from qualitative research to explore themes and concerns in more depth and support development and targeting of key messaging.

Summary Box

WHAT IS ALREADY KNOWN ON THIS TOPIC?

1. Very little is known about public perceptions of risk of exposure to COVID-19 and engagement with clinical and research provision in secondary care.
2. This research explores public perspectives in five key areas in order to inform health policy and both population and individual communication regarding attending secondary care sites for clinical and research activities.

WHAT THIS STUDY ADDS?

1. Insight into public risk perceptions specific to attending hospital during the COVID-19 pandemic
 - a. There are distinct groups of people who do feel safe and those who do not
 - b. Use of personal protective equipment, social distancing measures and cleaning are essential to supporting feelings of safety and are well supported
 - c. Recruitment to vaccine and COVID-19 studies presents challenges, especially amongst women and BAME respondents
 - d. Most people are very comfortable with new ways of working (i.e. remote/digital)
 - e. There is very strong support for continued health science research
2. Insight into the differences in perceptions and attitudes by individual risk status (due to age or comorbidity), sex and ethnicity.

Introduction

The novel infectious disease COVID-19, first identified in December 2019, has swept across the globe reaching pandemic levels with 12,685,374 confirmed cases and over half a million deaths.(1) It has led to significant changes in healthcare provision and clinical research activities associated with change in demand, practice and policy. In March 2020, the National Institute of Health Research (NIHR) Clinical Research Network suspended any new or ongoing studies at NHS and social care sites that were not nationally prioritised COVID-19 studies. The rapid reconfiguration of services meant many dedicated research personnel moved to the healthcare frontline, and remaining research personnel refocused work on COVID-19. Similar changes occurred in healthcare, with non-urgent clinical activity suspended and new, remote ways of working introduced to protect both patients and healthcare personnel as the UK entered a lockdown in March 2020. The UK began its vigilant journey out of lockdown in May 2020 and as it enters late summer the temporary halt of the many clinical and research activities in secondary and tertiary care will be ending. The adoption of new ways of working amid risks of initiating a second peak within the UK prompts a need for information on public opinion around attending hospital.

The importance of public involvement in all aspects of clinical and research activity is well recognised and enshrined in policy and procedures throughout health and social care; it's relevance to the COVID-19 pandemic is reaffirmed by the NIHR (2). Public involvement improves the quality and relevance of research, (3) and though rapid escalation of research considering COVID-19 makes involvement more challenging these benefits are worth retaining. Public involvement can help researchers understand public perception of risk as the driver of a range of pandemic-related behaviours, (4) such as compliance with lockdown requirements, adoption of protective measures like mask wearing and social distancing, and wider engagement with services including health, screening, social care and education and therefore support communication efforts (5).

Understanding of public feelings of safety, perception of factors affecting feelings of safety, intention to participate in research, comfort with new ways of working and attitudes to research will support efforts to ease lockdown in the sensitive hospital environment and is a key component of NIHR Restart project (6). Procedures, and particularly communication, around restarting clinical and research activities within hospitals need to incorporate the public voice to maximise chances of success. Failure to ensure patients and research participants feel safe within the hospital could have wide ranging impact from failure to access necessary healthcare highlighted by the 57% decrease in A&E attendance in April 2020 (7), postponement or failure to access necessary treatment (8), successfully delivering key metrics for research outside of COVID-19, and failure to recruit to research essential to tackling COVID-19. Furthermore, communication and perception of risk is poorly understood and has potential to impact public trust in science (9).

We aimed to rapidly assess public attitudes to attending hospital across the UK for research purposes and clinical appointments.

Methods

STUDY PARTICIPANTS

We developed an English language online survey in partnership with the NIHR Leicester Biomedical Research Centre Bioinformatics Hub in Research Electronic Data Capture Software (REDCap). The survey featured 1) participant information, 2) screening against inclusion/exclusion criteria and 3) survey questions. The survey was administered between 11 and 24 June, 2020, where lockdown restrictions were still in place across UK (England, Scotland, Wales and Northern Ireland). The link was shared via email and posted on social media (including websites, Twitter, and Facebook) by the NIHR Leicester BRC, the Leicester Diabetes Centre, the Centre for Black and Minority Ethnicity (BME) Health and NIHR PPI Leads nationally. Social media posts were sharable to facilitate snowball sampling.

STUDY PARTICIPANTS

The eligibility criteria were broad to maximise reach. We used the following inclusion criteria: 1) age 18 years or over; 2) resident in the UK; and 3) willingness to participate. Screening questions prevented completion in case of ineligibility

SURVEY QUESTIONS

Participant characteristics age, sex and ethnicity were collected, and whether they considered themselves classified at risk of COVID-19 because of a health condition (yes vs. no) or their age (yes vs. no). The questionnaire focused on perception of risk when attending hospitals during the pandemic. A 100-point Likert scale ranging from disagree (0) to agree (100) for each statement created by the researchers was presented with a simple interactive sliding scale. In total there were 42 statements: 11 explored current feelings of safety; 13 explored factors affecting feelings of safety; 4 explored intention to participate in research; 8 explored attitudes towards research; and 6 explored comfort with new ways of working. In addition, the opportunity to provide free text responses related to participants' safety concerns was provided. The data from the free text fields are not included in this manuscript. Further details are provided in **Supplementary Methods S1**.

PATIENT AND PUBLIC INVOLVEMENT

The survey was considered public involvement to inform the Leicester strategy for recommencement of clinical and research activities. It was soft launched to the Leicester PPI Groups, to gain initial data and feedback on any issues, with a full launch 3 days later. As no changes were required, the initial data is included in the full results.

ETHICS APPROVAL AND INFORMED CONSENT

The survey included participant information, which remained accessible throughout survey completion. The screening questions included Boolean consent, as per best practice for remote consenting to non-interventional research. A clear explanation of the purpose of the survey, data handling, potential burden and benefits of participation was provided, and participants were prompted to carefully consider their willingness to participate.

This research has been reviewed by the Medicine and Biological Sciences Research Ethics Committee of the University of Leicester (ref:26258-rp237-ls:healthsciences).

STATISTICAL ANALYSIS

Descriptive analyses were performed. The continuous 100-point Likert scale was assessed for normality using histograms and the Shapiro-Wilk test. The distribution of all responses was found to be not normally distributed, therefore the median value and interquartile range (IQR) were used to present the findings. The responses were also stratified into four key groups: 1) whether or not the participant was classified at risk of COVID-19 because of a health condition; 2) or due to their age; 3) by men and women; and 4) White European or Black, Asian or Minority Ethnicity (BAME). The two-sample Wilcoxon rank-sum (Mann-Whitney) test was used to calculate whether there was a significant difference between groups, the statistical significance was set at $P\text{-value} < 0.05$ (two-sided). Results are reported as median Likert scale followed by the interquartile range (median (IQR)). Participants were not required to answer every statement; thus, the total number of responses slightly vary due to missing data. Data from REDCap was exported into Stata version 16.0 to conduct data analyses.

Results

PARTICIPANTS' CHARACTERISTICS

A total of 402 participants completed the survey questionnaire. Of those, 192 (48%) reported they were at risk of the COVID-19 due to a health condition, and 286 (71%) due to their age. Participants age ranged from the 18-24 age group to 85+, where the majority (337 (84%)) were aged between 35 to 74 years. There were a higher number of women (77%) compared to men (23%); and were mainly White (91%) compared to BAME (6%), or other (2%), as shown in **Table 1**.

PERCEPTION OF ATTENDING HOSPITALS

Current feelings of safety (11 statements)

Data are shown in **Figure 1**. Participants agreed they felt most safe and confident about coming to the hospital for essential surgery (median 78 (IQR 39-96)), followed by a clinical scan or x-ray, (median 77 (IQR 34-94)); and a clinical blood test (median 77 (IQR 35-94)). Whilst participants felt least safe and confident attending the Accident and Emergency (A&E) (median 50, IQR 21-85); or visiting a friend or family member in hospital, (median 49 (IQR 15-75)).

These findings significantly differed by those with a health condition compared to those without a health condition, as the responses on the Likert scale were much lower for all 11 statements. Particularly visiting a friend or family member in hospital with a health condition compared to those without a health condition, (median 33 (IQR 8-65) vs. 68 (IQR 32-90), respectively $p < 0.001$), attending the A&E (median 36 (IQR 12-78) vs. 68 (IQR 33-90), $P < 0.001$, respectively) or taking part in research (median 47 (IQR 12-81) vs. 73 (IQR 36-90), $P < 0.001$, respectively). **Supplementary Table S1**. Similarly, women felt least safe and confident coming to the hospital compared to men, and those from a BAME background compared to those from a White European background. The BAME sample rated the Likert scale the lowest, even for coming to hospital for an essential clinical appointment (median 29 (IQR 21-57), $P = 0.003$), investigative clinical appointment (median 35 (IQR 21-67), $P = 0.008$), or clinical blood test (median 39 (IQR 18-70), $P = 0.028$). There were no significant differences by participants who thought their age put them at increased risk of COVID-19 (**Supplementary Table S1**).

Factors affecting feelings of safety (13 statements)

In order to feel safe in the hospital environment the highest score on the Likert scale was to see consistent use of personal and protective equipment (PPE) such as gloves and masks, (median 95 (IQR 83-99)); to be reassured that careful cleaning measures were in place (median 95, (IQR 80-99)); to see strict social distancing measures in place (median 90 (IQR 76-98)); and to see as few staff as possible i.e. rather than seeing a doctor and having a nurse take a blood sample, everything is done by one person (median 82 (IQR 64-96)), as demonstrated in **Figure 2**. When stratifying the results, these statements were found to be mostly higher in those with a risk of the COVID-19 due to their health condition or age. Compared to the White European ethnicity, the BAME sample showed they felt safe in the hospital if they were reassured that staff have been tested negative for the COVID-19 infection (median 90 (IQR 77-95) vs. 76 (IQR 50-96), $P = 0.041$, respectively), and also to attend research visits somewhere other than a hospital (median 89 (IQR 70-100) vs. 69 (IQR 49-87), $P = 0.006$, respectively), **Supplementary Table S2**.

Intention to participate in research (4 statements)

Most participants would come into hospital to take part in research related to a medical condition (median 75 (IQR 49-96)); and in COVID-19 research which is not a vaccine study (median 70 (IQR 34-92)), **Figure 3**. The responses differed between men and women with men rating intention to participate in research more highly, and by risk of COVID-19 due to their health condition with those not at risk rating intention to participate in research more highly (**Supplementary Table S3**).

Attitude towards research (8 statements)

Participants felt since the COVID-19 pandemic it is more important than ever to do health research (median 94 (IQR 79-99)), and also disagreed to the statements: we need to invest less money and resources in research (median 6 (IQR 2-21)); and were less interested in health science and research (median 6 (IQR 2-20)), as illustrated in **Figure 4**. Some of the statements varied by age, sex and ethnicity, **Supplementary Table S4**. This shows that those at risk due to age agreed that it is important to do research, disagreed with investing less in research, and disagreed they were less interested in health science and research more strongly than those not at risk due to age. Men disagreed more strongly with women on all statements about researchers asking participants into hospitals to do research. White participants agreed more strongly that it is important to do research, and disagreed more strongly that they are less interested in health and science, than BAME respondents.

New ways of working (6 statements)

The results in **Figure 5** illustrates that participants were comfortable with new ways of working, as the results were very high for all statements. The 6 statements significantly differed between sex and ethnic groups (**Supplementary Table S5**). We found the responses were lower in BAME than those from a White background in the following statements: sharing my medical information, for research purposes using an online form or app (median 51 (IQR 11-90) vs. 95 (IQR 75-99), $P < 0.001$), giving consent to take part in a research project using an online form or app (median 52 (IQR 24-89) vs. 96 (IQR 76-99), $P < 0.001$, respectively), and women rated their comfort as lower compared to men across all scales, **Supplementary Table S5**.

Discussion

The purpose of this work was to rapidly assess public attitudes to attending hospital across the UK for research purposes and clinical appointments. The findings showed patterns of response that may support efforts to recommence clinical and research activity in secondary care. Of particular note are findings around differences between the perceptions and attitudes of women and BAME respondents suggesting a need to consider how current changes in activity might disproportionately impact some groups in society.

There is very little previous research into the risk perceptions associated with COVID-19, though our findings do reflect the paradoxical finding of (10) that men are more at risk than women (11), but women perceive greater risk than men. This is of particular interest as men are at greater risk but consistent with a large body of research showing women perceive greater risk than men across a range of activities (seatbelt use, smoking, environmental hazards). However, the lack of gender differences in respect of factors effecting feelings of safety would suggest the effect is underpinned by a requirement to see safety measures implemented i.e. the effect is a mix of the cognitive and emotive.

The differences between ethnic groups with lower scores for feelings of both safety and intention to participate in research and/or attend clinical appointments in our BAME responders is particularly relevant. The disproportionate risk of contracting COVID-19 (12) and poorer outcomes in BAME groups compared to white counterparts (13) is a recognised public health issue. Public Health England has engaged with key stakeholders to start the process of understanding this health inequality and discuss strategies to reduce the direct and indirect impact of this pandemic and indeed any future pandemic. The results presented here add to the growing evidence for the need to work with local communities to reduce fear and rebuild the BAME communities trust in the health services. Strategies must be sought to increase attendance for routine appointments need to be considered including increasing accessibility by bringing care to our BAME communities. Further, as new recruitment efforts for COVID-19 research commences; a focus on working with the BAME communities is required to permit adequate ethnic representation in health research because insufficient diversity in recruitment has consistently underpinned and exacerbated health inequalities. The lower feelings of comfort with new ways of working also highlights a potential area for further exacerbation of health inequality in service provision indicating services need to be patient-centred and offer choice of mode of contact.

The high perception of risk in attending Accident and Emergency (A&E), is notable and in line with recent findings (5). These results mirror what has been observed nationally with dramatic reduction in attendance to A&E and emergency admissions, April saw a staggering 57% drop compared to the same month in 2019 (7). The question is whether this is a positive change in public behavior or has this added to the indirect impact of COVID-19 on health. In, both scenarios work is required with the public and health systems to either continue diverting 'treatment seeking' away from A&E where it is not necessary or breakdown this new fear in seeking emergency care.

Histograms for scales (not shown) showed there was a distinct grouping of respondents into those who felt safe and those who did not, with generally few people in the middle. This was partially accounted for by differences associated with sex and ethnicity though interestingly there was no effect of age-related risk. Other factors may be associated with the bipolarity of responses, such as worldview, political inclination and sense of individualism, as identified in other recent research (10).

The factors effecting feelings of safety provide information on what participants expect to see when attending hospital. The highest rating for consistent use of PPE reinforces the recent decision to enforce use of PPE in hospitals by both visitors and staff in all areas. Findings suggest hospital attendees and particularly those at risk because of age/ comorbidity will also need to see strict cleaning procedures and social distancing. BAME respondents additionally rated off site research visits and staff antibody and swab testing as important to their feelings of safety. In order to ensure representative recruitment to research and particularly rapid research around COVID-19, it will be important to consider how needs differ for potential BAME research participants in order to avoid perpetuating health inequalities.

Women and those at risk due to comorbidity were less likely to participate in research suggesting potential participants consider personal relevance of the research and societal urgency when deciding if they will participate. This highlights a specific recruitment challenge when considering vaccine trials for COVID-19 that will need to recruit people with comorbidities. Escalation of vaccine research will require large-scale public facing recruitment that has not been attempted previously in the UK.

The respondents overall attitude to research indicate a strong continued support for participation, interest and investment in health science research though ambivalence about prioritising COVID-19 suggests this is partially generic. The pandemic, and increased health science coverage in the media, provides an opportunity to increase engagement across the board, with age-related disparities suggesting there is a need to engage younger/working age populations. Respondents again balanced risk with personal and social necessity, finding it most acceptable to be asked to attend a hospital for COVID-19 research and least so for healthy volunteer studies, with a near-significant lower acceptability for those with comorbidity.

Communication professionals should consider pre-recruitment engagement and messaging in order to 1) prime a new audience for recruitment into vaccine studies that have typically relied on staff and student recruitment and 2) prime under-represented audiences with good quality information on risk and risk management to support recruitment efforts.

Finally, respondents reported high levels of comfort with digital and remote ways of working which is reassuring for clinicians and researchers. However, our aging and BAME communities needs considering given the reported differences in preferences.

A limitation of this work is the much smaller number of BAME respondents (6%) compared to White (91%) resultant from the need to be responsive this survey was undertaken rapidly, in just 2 weeks and only in English. Due to the limited nature of the sample therefore it is important to be cautious generalising especially as we found significant differences by ethnicity.

Conclusions

We believe this is the first study in the UK to assess public opinions of attending hospitals during the rapid rise of the COVID-19 outbreak, which is particularly relevant to national activity around recommencing clinical and research activity.

As some of the most interesting findings pertain to groups under-represented in the sample it follows that further research into the thoughts and feelings of BAME communities and women would be informative. The patterns of risk perception suggest there may be complex processes underpinning individual assessment of risk, widely recognised as subjective (5), which might be explored more with qualitative research methodology. Focus groups are underway to explore this, and vaccine study recruitment, in more depth so diverse perspective can support both clinical and research activity post-COVID-19.

Healthcare needs to be accessible to BAME communities and women so alterations to practice need to take into account the differences in preference and include a flexible approach to the delivery of care.

Information

FUNDING SOURCE

There was no specific funding for this project. Staffing was funded through infrastructure funding for the NIHR Leicester BRC.

AUTHOR CONTRIBUTIONS

Ranjit Arnold proposed consulting patients around hospital attendance for imaging and tests. RP, GM and EB developed the study design and survey in detail, expanding to include wider research and clinical concerns and aligned to the Restart project. Sue Sterland created the REDcap survey in consultation with RP. RP engaged the NIHR PPI Leads, local NIHR colleagues and University Hospitals of Leicester Trust to disseminate the link nationally, and via her own local PPI mailing lists. YC undertook statistical analysis and associated presentation of data. RP, EM, YC, GM worked on the manuscript collaboratively.

ACKNOWLEDGEMENTS

The support of the NIHR PPI Leads Network with dissemination of the link for data collection is acknowledged.

DATA ACCESS AND RESPONSIBILITY

The data is accessible to RP, SS, YC, EB and GM. It is the responsibility of RP.

DECLARATIONS OF INTERESTS

This activity may contribute to the PhD studies of RP.

No other interests are declared.

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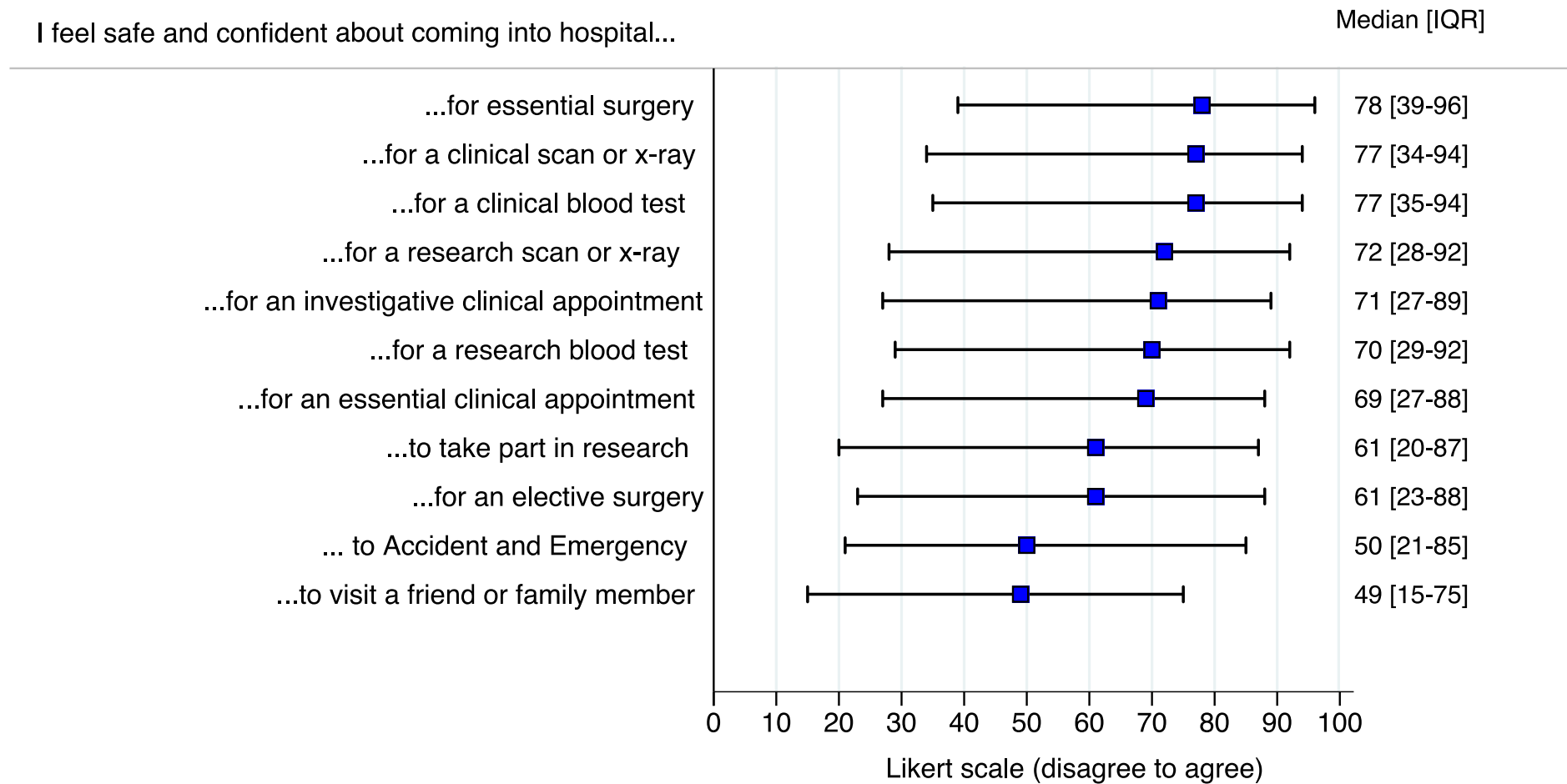
Tables

TABLE 1. CHARACTERISTICS OF PARTICIPANTS WHO RESPONDED TO THE SURVEY BETWEEN 11 AND 24 JUNE, 2020 (N=402)

CHARACTERISTICS	NO. (%)
Risk of COVID-19 due to a health condition	
Yes	192 (47.8)
No	207 (51.2)
Missing	3 (0.8)
Risk of COVID-19 due to age	
Yes	286 (71.1)
No	109 (27.1)
Missing	7 (1.7)
Age group	
18-24	7 (1.7)
25-34	25 (6.2)
35-44	52 (12.9)
45-54	72 (17.9)
55-64	98 (24.4)
65-74	115 (28.6)
75-84	30 (7.5)
85+	3 (0.8)
Sex	
Women	308 (76.6)
Men	94 (23.4)
Ethnicity	
White	366 (91.0)
BAME (Black and Minority Ethnicity)	22 (5.5)
Other	8 (2.0)
Missing	6 (1.5)

Figures

FIGURE 1. PARTICIPANTS RESPONSE TO THEIR CURRENT FEELINGS OF SAFETY WHEN ATTENDING HOSPITALS BETWEEN 11 AND 24 JUNE, 2020

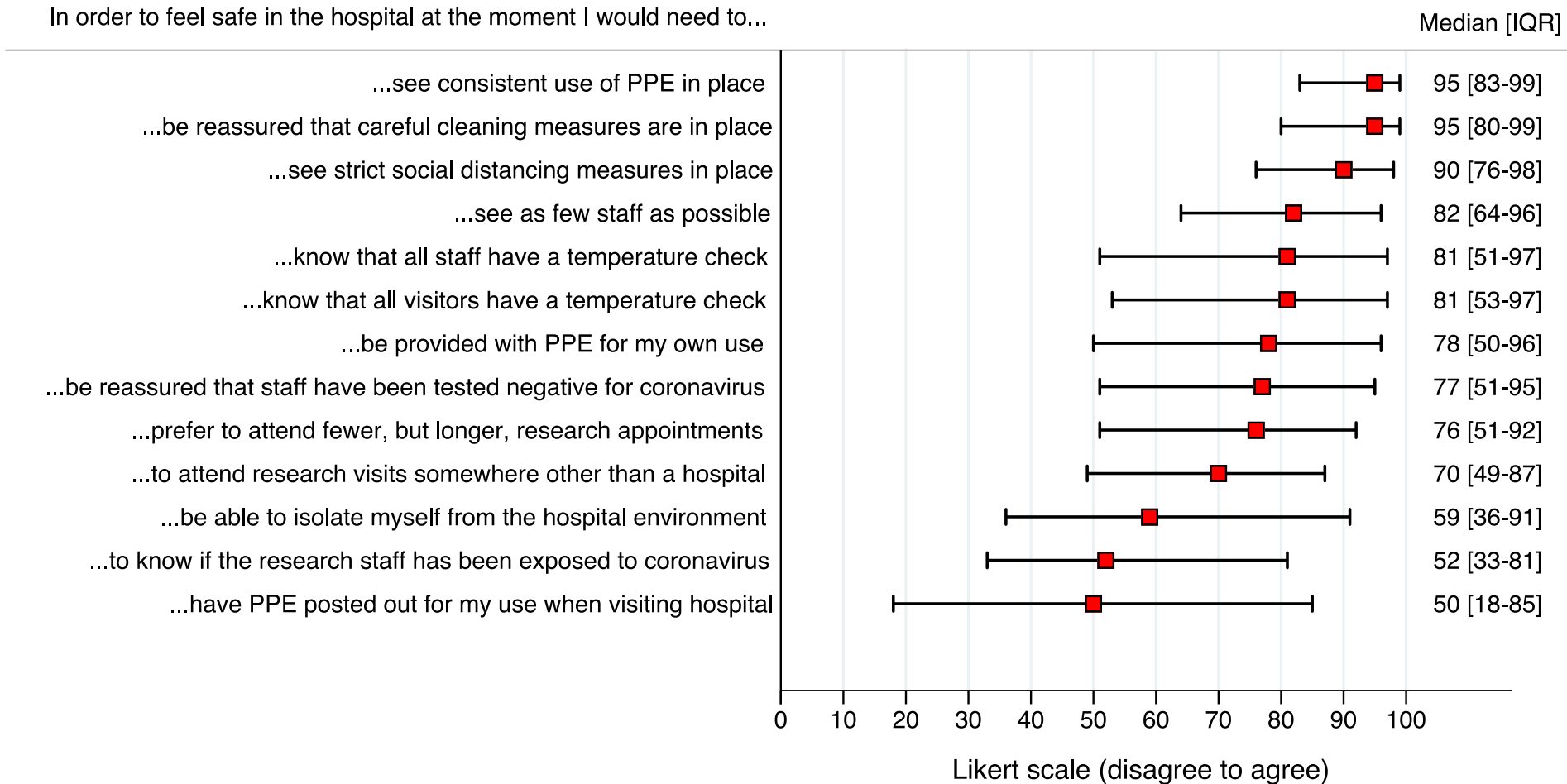


IQR=interquartile range; PPE=personal protective equipment, i.e. gloves and masks.

100-point Likert scale ranging from disagree (0) to agree (100) for each statement, presented with a simple interactive sliding scale.

The statements have been shortened and placed in descending order for the purpose of illustration; full details can be found in Supporting Methods S1

FIGURE 2. PARTICIPANTS RESPONSE TO FACTORS AFFECTING THEIR FEELINGS OF SAFETY WHEN ATTENDING HOSPITALS BETWEEN 11 AND 24 JUNE, 2020

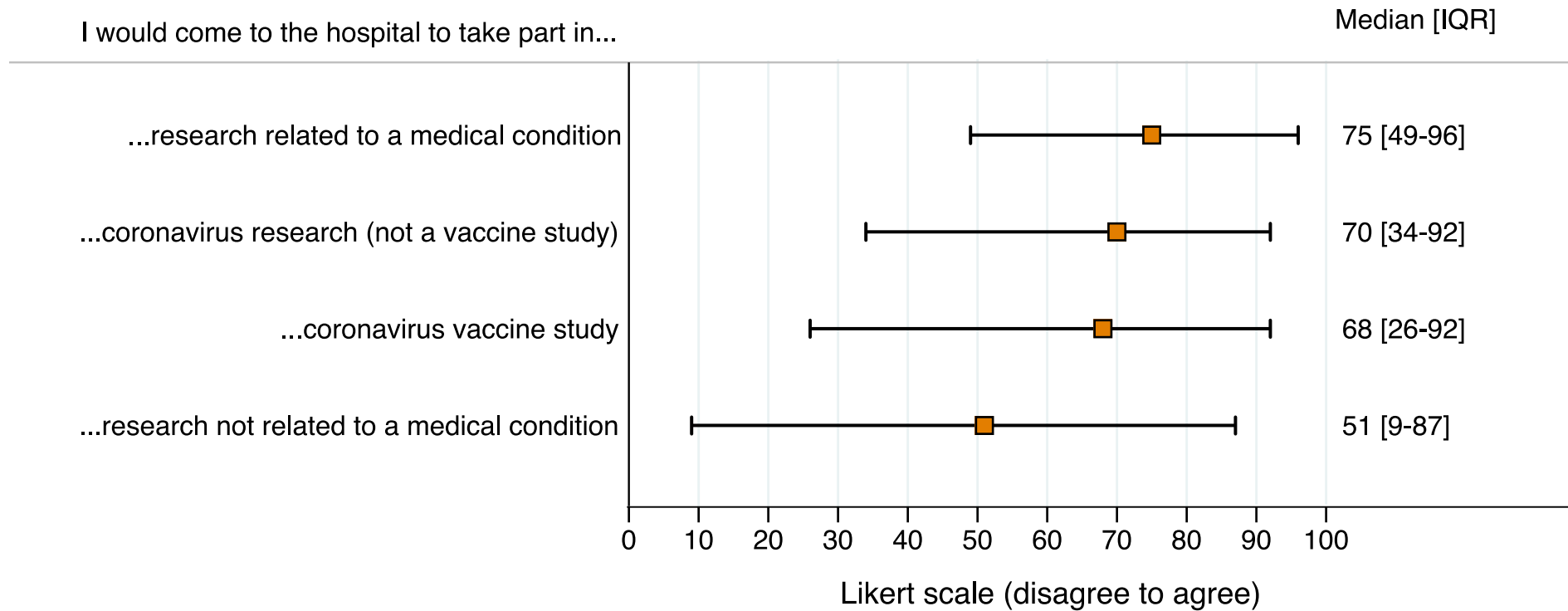


IQR=interquartile range; PPE=personal protective equipment, i.e. gloves and masks.

100-point Likert scale ranging from disagree (0) to agree (100) for each statement, presented with a simple interactive sliding scale.

The statements have been shortened and placed in descending order for the purpose of illustration; full details can be found in Supporting Methods S1.

FIGURE 3. PARTICIPANTS RESPONSE TO THEIR INTENTION TO PARTICIPATE IN RESEARCH BETWEEN 11 AND 24 JUNE, 2020

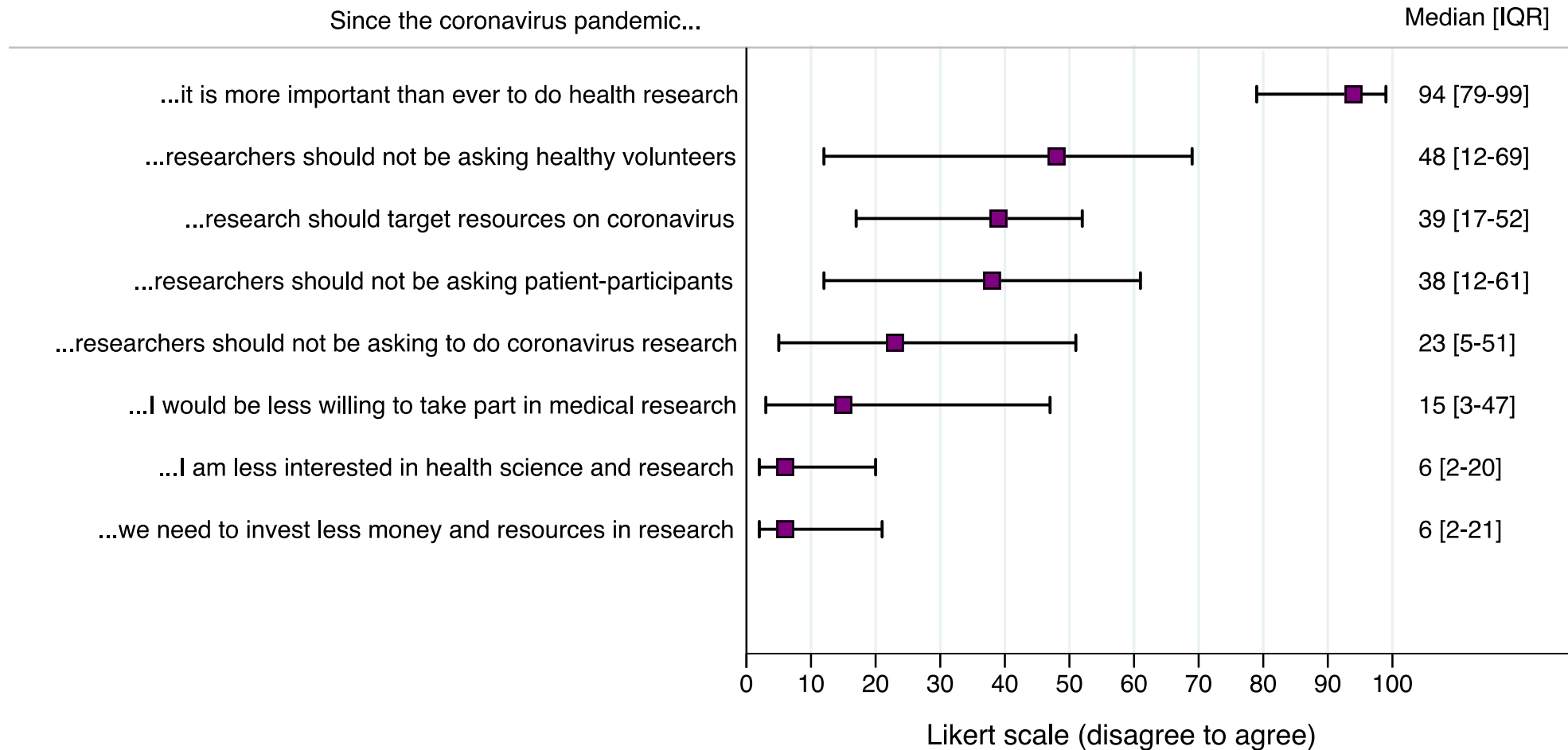


IQR=interquartile range.

100-point Likert scale ranging from disagree (0) to agree (100) for each statement, presented with a simple interactive sliding scale.

The statements have been shortened and placed in descending order for the purpose of illustration; full details can be found in Supporting Methods S1.

FIGURE 4. PARTICIPANTS RESPONSE TO THEIR ATTITUDE TOWARDS RESEARCH BETWEEN 11 AND 24 JUNE, 2020

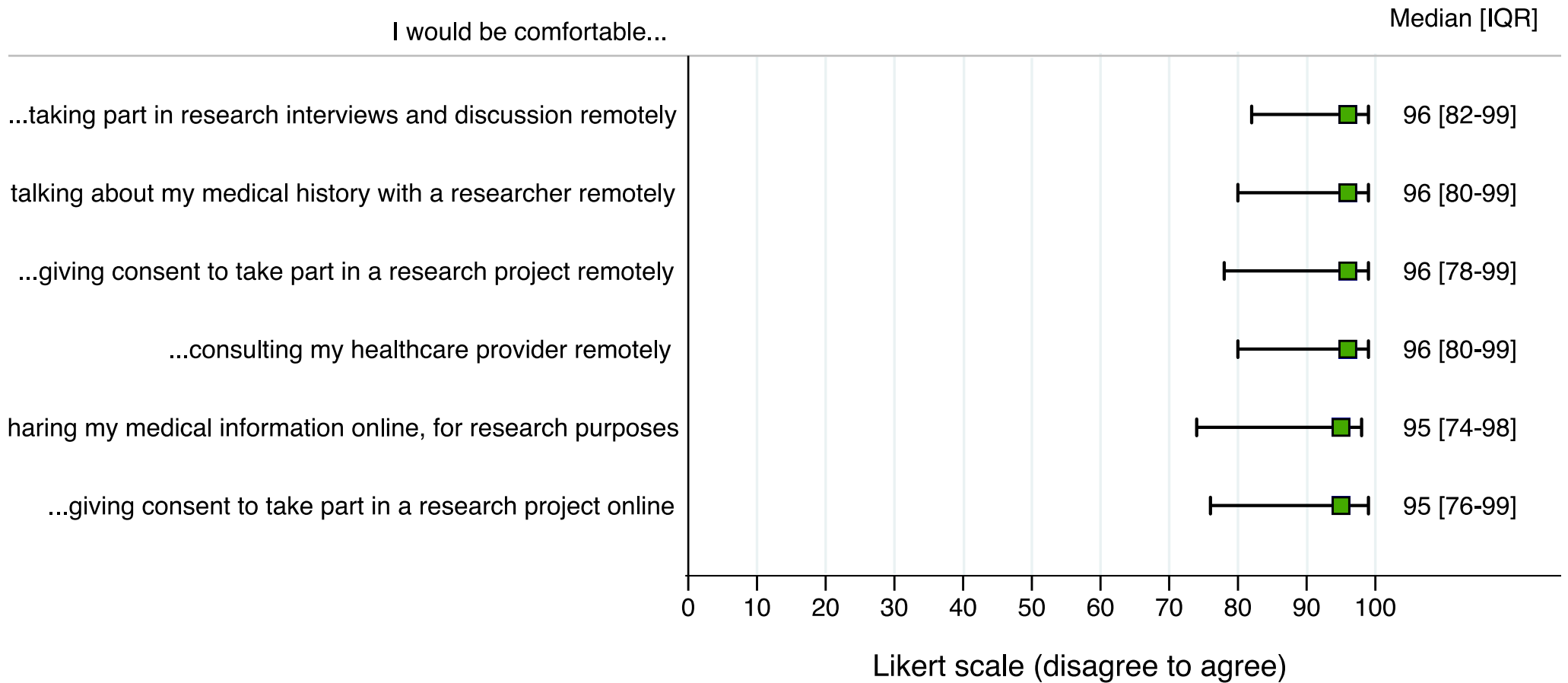


QR=interquartile range.

100-point Likert scale ranging from disagree (0) to agree (100) for each statement, presented with a simple interactive sliding scale.

The statements have been shortened and placed in descending order for the purpose of illustration; full details can be found in Supporting Methods S1.

FIGURE 5. PARTICIPANTS RESPONSE TOWARDS NEW WAYS OF WORKING BETWEEN 11 AND 24 JUNE, 2020





Appendix 2

NHS
University Hospitals
of Leicester
NHS Trust

Caring at its best

How did we get here? Reflections on how UHL became a top research recruitment site during COVID-19

A Briefing Document for UHL Trust board and Leicestershire Academic Health Partners board

Research is the world's best exit strategy for the coronavirus pandemic – Wellcome Trust

Contents

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Introduction

This document summarises the key reflections of the UHL R&I senior leadership team as to how Leicester became the top recruiting site to the RECOVERY trial and other urgent public health priority studies during the coronavirus pandemic. While the national average for recruitment into COVID-19 clinical trials was 13 per cent, over half of patients hospitalised with COVID-19 at UHL were enrolled into interventional research. 95 per cent of patients with COVID-19 were entered into at least one observational study. In doing so, Leicester has been held up a national model of excellence by UKRI and DHSC.

In setting out these reflections, we endeavour to harness the best practice and new ways of working so they can be embedded in future.

Background

There are approximately 1,000 studies taking place at UHL every year, recruiting circa 13,000 participants. When the scale of the pandemic was evident, it was recognised that research on this scale could not continue in its present form.

From early on, research was quickly put front and centre as the UK and global exit strategy to a disease with no known cure. There were four main foci: reliable tests (detection of current virus and detection of antibodies); understanding who was most at risk; treatments for the sick; a vaccine.

Under the direction of the CMO, the NIHR set about a rapid review system for proposed studies and badged those it felt would most likely yield good evidence on risk factors, treatments and prevention as 'urgent public health' studies. Chief executives of NHS trusts were encouraged to ensure these studies were carried out, and carried out well, on their sites. Since then UHL has become one of the top, if not the top, recruiting site to each of the UPH studies we have opened at our sites. How did that happen?

Strong strategic leadership

A few months prior to the outbreak, the R&I leadership model was reformed. This has made a significant impact on the direction and velocity of travel for the research workforce during the pandemic. Rather than fracturing and each part of the research infrastructure pursuing its own agenda, the triumvirate of R&I Director / CRF Director, Associate R&I Director /BRC Director and Respiratory theme / NIHR national Respiratory Translational Research Collaboration (TRC) lead have worked co-operatively rather than competitively.

This co-operation and open communication has ensured that resources have been rapidly deployed to areas of critical need. The leadership team has prioritised areas outside of their own interests so the immediate need can be met.

The leadership team has made it their business to be well informed about the local, regional and national picture as it relates to the pandemic and shared that intelligence in regular catch ups in order to inform the next steps in planning and execution for Leicester.

The leadership team has been very clear about communicating a single message regarding Leicester's response to the pandemic. This has been reinforced and reaffirmed in individual and

team meetings across the infrastructure by the research leaders. There has been little or no room for uncertainty or lack of clarity of vision for Leicester's response and priorities for the research team.

Single unifying purpose

Once the pandemic took hold, R&I had two key goals: (a) support frontline clinical services where needed, and (b) recruit to COVID-19 priority studies. There has been exceptional clarity on the this strategy, which has been communicated without ambiguity to research managers and teams, not in a didactic manner but through mutual agreement that this was the correct approach in these unique circumstances.

This has been achieved against a backdrop of rapidly changing and sometimes confusing national and regional communications from DHSC and supporting bodies. Despite this, research staff have understood their purpose and responded without hesitation to the tasks allocated to them.

Strong operational leadership

Team leaders have supported their teams and consistently implemented the R&I strategy through a period of unprecedented uncertainty. This has been made possible because of a previous investment in developing trust and joint working processes and practises over the preceding 12 month period.

Prior to this, the research infrastructure had existed and worked to a degree of mutual isolation. Investment in a chief operating officer and head of research nursing has seen research teams interacting with greater frequency and to common purposes, such as sharing SOPs, moving staff to support gaps in teams, and sharing intelligence and experience. Building trust such that when the need to throw the 'old' ways of working out of the window became a necessary, team leaders showed flexibility and mutual support for other teams and thus were well prepared to meet the challenges of the pandemic head on.

Communications

The rapid establishment of a weekly clinical research activity and COVID video call has enabled rapid dissemination of information up and down the research hierarchy. Consistency of chairperson and commitment from key individuals - including all senior R&I leaders, research managers and a large number of principal investigators - to attend regularly and contribute has ensured that the weekly brief filters through the entire research infrastructure. It guides much of the decision making and aids clarification of issues and instructions in real time. The breadth of attendees also helps with effective communication; as such the call has more than 50 individuals from across the research infrastructure.

Research communications has been firmly embedded into corporate communications during this time, providing back-up to the corporate team as well as developing research-led stories. Research has been a source of positive news against a backdrop of death announcements and other negative stories. It has helped drive the external reputation of the organisation and contributed motivational material to internal briefings. Its integration into corporate channels has ensured buy-in across UHL that research is everyone's business.

Trust in governance processes

Trust in the system has been of paramount importance. There exist multiple strong relationships across the country between the regulatory authorities (e.g. HRA) and our governance structures. It has been evident that the time taken to forge these individual relationships and develop a mutual trust over many years has resulted in confidence in the wider system. All the COVID-19 response research adopted under the Urgent Public Health initiative has been authorised by UHL within a few days, and amendments often within hours. In addition, and of equal importance, trust in the clinical teams has been critical. Checks to make sure that the clinical services and relevant support services have capacity is done, confirmed by email and the study has been good to start. The other documentation, recording of information and so on, is completed after the fact. This is possible not only because of our pragmatic and proportionate approach, but also because we are all focused on our single unifying goal.

Size of the organisation

The number of research staff employed directly by the NHS trust is around 350 members; this doesn't account for the other clinical academic, clinical and university employees who we would also consider to be part of the research team in Leicester. The size of the team is large enough to be able to deliver effectively, but not so large that communication and operational / strategic planning breaks down because teams are too far from the centre. There is a very pragmatic decision making process centrally which seeks to support and co-ordinate the federated infrastructure, including CRF and BRC, rather than control and impose operational control. While geographically we are separated by a few miles over different sites, operationally we have been able to continue to support research and clinical service in every clinical division within the trust. This makes the team optimal for decision making and big enough to cope, while small enough to care.

Flexibility and commitment of delivery staff

The immediacy and willingness of delivery staff to support clinical service, and more latterly to work across site and speciality within the federated structure has been a fantastic testament to the integrity and commitment of delivery staff. The successful transition from independent clinical management groups (CMGs) to one R&I team has underlined how effective and efficient the workforce can be when the final goal is correctly assessed. Planning and implementation strategies, are routinely discussed between the R&I senior leadership team and the local specialty research managers. The latter are the "linchpin" between strategy and research operations. A thorough assessment of individual team members' clinical skills has guaranteed frontline clinical service cover during the peak of the pandemic, as well as research delivery on priority studies. Research staff allocation was assessed on a weekly basis, which guaranteed a realistic use of resources where needed and at short notice. Staff recognised the importance of team working, skill mix and knowledge transfer.

Conclusions and next steps

The success of Leicester's research during COVID-19 can therefore be summarised as:

- Strong strategic leadership team who outlined a single, unified purpose for the service early on in the pandemic, backed up by strong operational managers overseeing a flexible and committed delivery staff

- A large but not overinflated research workforce with the capacity to scale up studies rapidly, but not so large that staff felt alienated from the centre
- A well- connected service linked to national and regional scientific and governance networks, and holding positions of influence within them; backed by integrated communications that linked the service internally to the corporate communications channels while delivering external communications to media and stakeholders on a regular basis

The R&I senior leadership team at UHL proposes to share the experiences and best practice developed during this time at an event in early 2021 and would be keen to work with other research partners across Leicester and Leicestershire on the content, format and delivery of such an event.