

Advanced Clinical Practitioners in clinical research – Opportunities and challenges to transform research delivery.

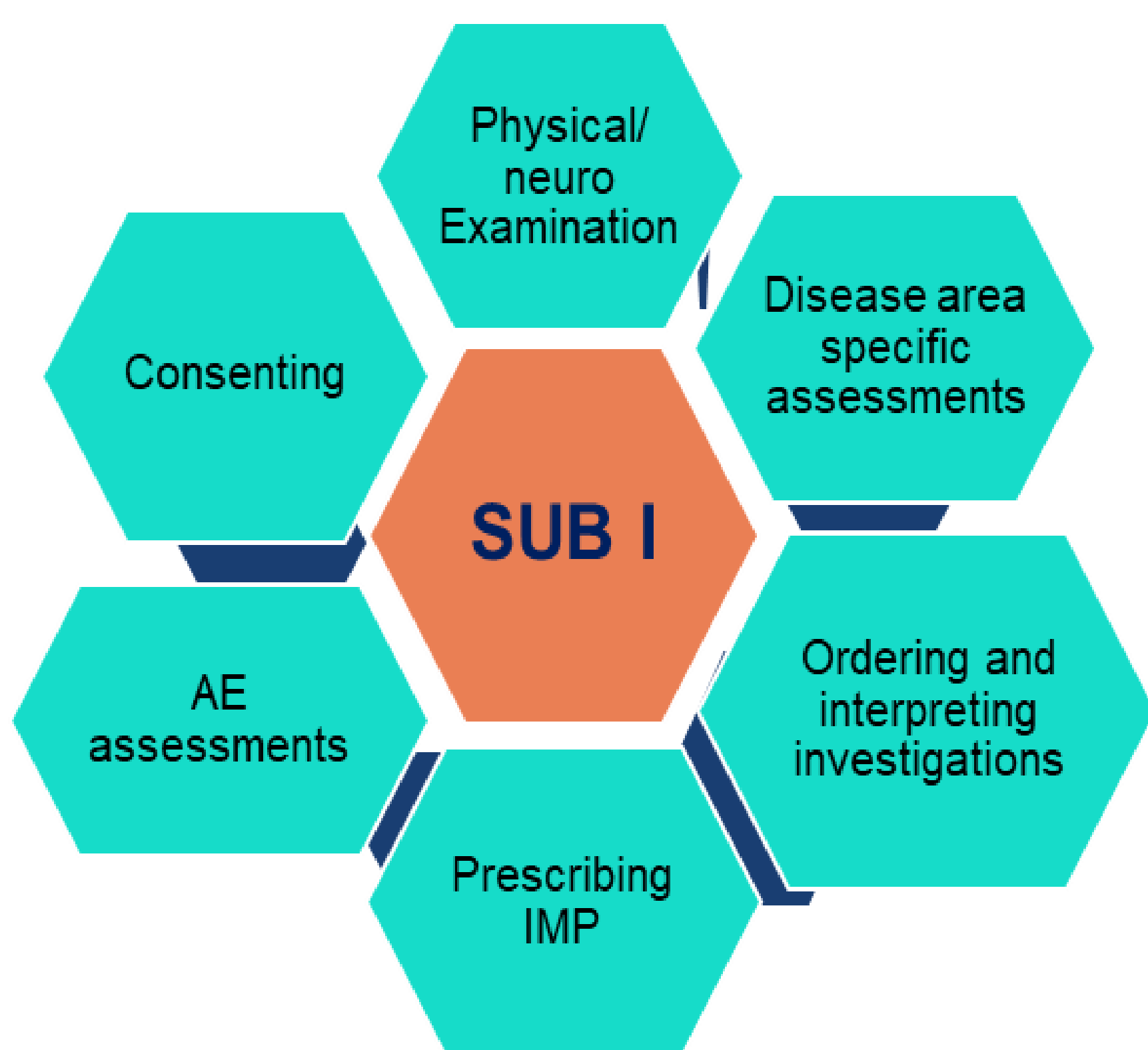
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Introduction

The Advanced Clinical Practitioner (ACP) in clinical research plays a pivotal role in providing safe and consistent medical management of adult and paediatric patients on clinical trials.

The aim of this poster is to highlight the ACP role in providing safe and effective research delivery prior to, and during the COVID-19 pandemic, the challenges faced by ACPs, how these are being addressed and the future innovation that these highly skilled, autonomous practitioners provide in a forever changing the NHS research landscape.

ACPs as Sub Investigators



Sustaining research delivery during the COVID-19 pandemic

- Clinical research faced significant challenges with many trials paused to recruitment and staff redeployed to the front line. ACPs in clinical research played a significant part in sustaining research activity in life saving priority trials that continued during the pandemic.
- Maintained the medical management and oversight of patients participating in trials.
- Provided medical cover for COVID-19 vaccine trials and were Principal Investigator(PI) for other COVID-19 studies.
- ACPs continued vital education and learning in areas such as vaccine administration, Advanced Therapies and simulated Emergency Scenario Training.

Challenges to autonomous practice

- Lack of a consistent interpretation and implementation of the terminologies detailed in GCP throughout the UK
- Lack of clarity of what constitutes PI oversight and which tasks can be delegated to ACPs in the UK
- Inconsistencies in approved clinical practices which ACPs can conduct in the UK

Terminologies used in Good Clinical Practice guideline(GCP)

- Who is a Sub-Investigator?**
1.56 Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial -related procedures and/or to make important trial related decisions. (associates, residents, research fellows) (EMA, GCP E6 R2 2016)
- CTA Part 2 Principles based on ICH GCP**
7. "The medical care given to, and medical decisions made on behalf of subjects shall always be the responsibility of an appropriately qualified doctor or when appropriate of a qualified dentist" Medicines for Human Use (Clinical Trial) Regulations 2004.
- Who should make causality assessment?**
5.6.1.1 Causality assessment decision must be made by a medically qualified doctor as these decisions require medical and scientific judgement to be used as well as knowledge of the subject concerned (GCP Guide 2012).

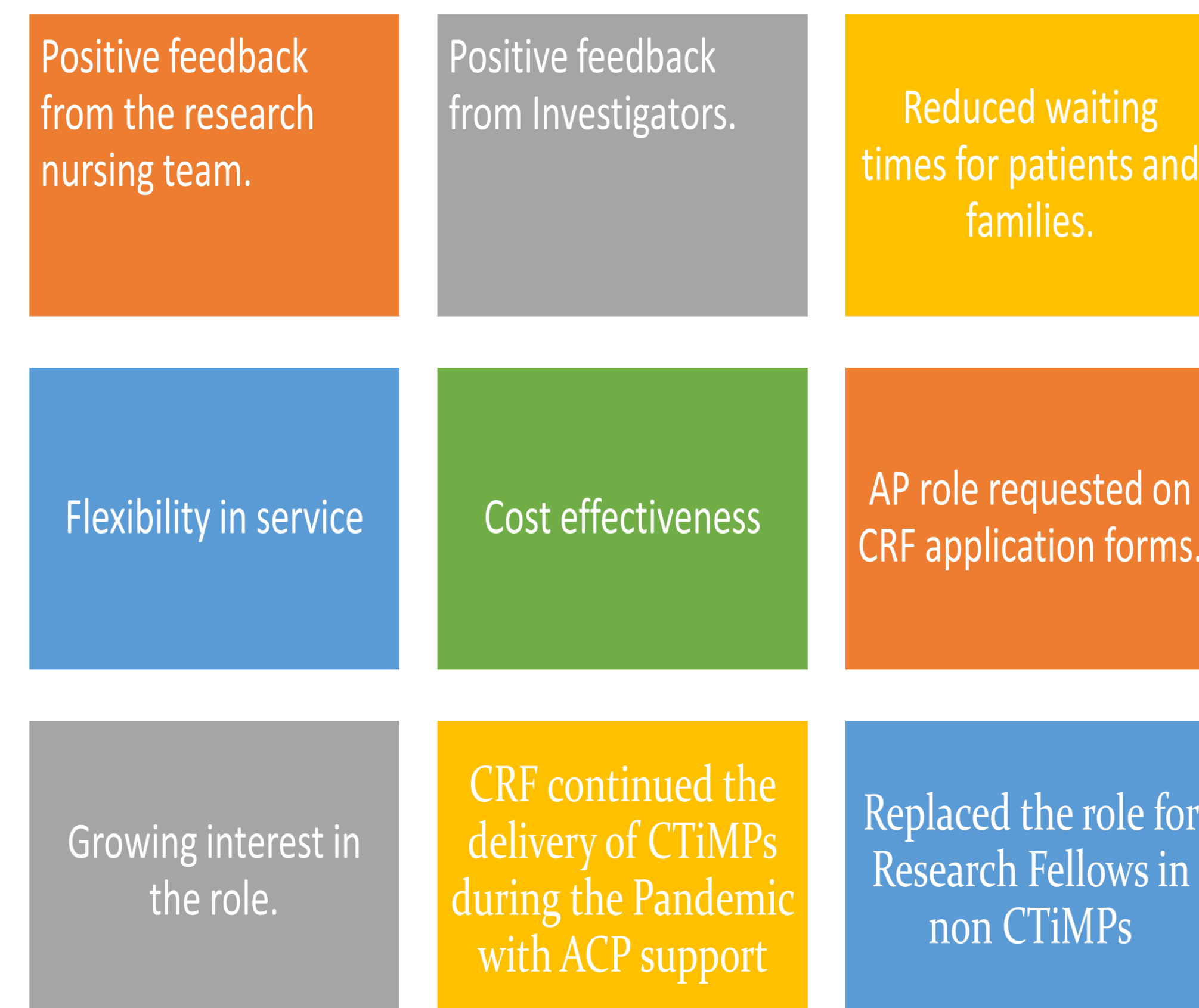
Impact of barriers on role development

- ACP role not utilised to its full potential
- Under utilisation of skills and experience.
- Decreased morale.
- Barriers in career pathway for future research nurses / ACPs.
- Barrier in achieving NIHR strategic focus on building the research capacity and capability and career structure for under- represented disciplines and specialisms.

Impact of barriers in service delivery

- Covid vaccine trials due to limitations around them 'assessing eligibility' for the trial.
- Extended recruitment period required to meet target recruitment.
- Delays in recruitment due recruitment drive to train new Research Fellows to assist with trial delivery.
- Significant impact on patient waiting times, experience and satisfaction.
- Additional costs incurred from the use of bank staff and new employments.
- Barrier in achieving (National Institute for Health and Care Research (NIHR)vision on modernising NHS and delivering timely research.

Role Evaluation



Future

- Innovation and flexibility for ACP roles in clinical research within primary and secondary care.
- Increased number of ACPs in clinical research .
- Recognition from key stakeholders of ACPs expertise and skills in research delivery.
- Development of more ACP led outreach models of clinical research delivery to increase access to clinical trials closer to home and increase patient referrals for more complex experimental cancer clinical trials.
- ACPs being the PI on an increased number of studies and trials.

Conclusion

The innovative use of the ACP role is paramount to sustaining a safe and effective workforce to deliver clinical research. Utilising the full potential of the ACP roles within their scope of practice will help accelerate clinical translational research delivery. In order to address the barriers, there needs to be a collaborative approach from all key stakeholders, including the NIHR and Medicines and Healthcare products Regulatory Agency(MHRA), to provide a pragmatic resolution that ensures the ACP role is fully utilised and further innovation can be achieved across all areas of clinical research.



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