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SWOT Analysis and Insights into the Health Research Authority Approval Process for COVID-19 Antimicrobial Stewardship Research in UK Secondary Care: Advocating Think Ethics

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Abstract

This article examines the Health Research Authority's (HRA) approval process, guided by the 'Think Ethics' principal, for an antimicrobial stewardship (AMS) research project at an English NHS Foundation Trust during the COVID-19 pandemic. Employing a SWOT analysis to reflect critically on the process, the project encompassed a retrospective examination of patient records and a survey of healthcare workers, navigating the application of the Integrated Research Application System (IRAS). The HRA's streamlined procedures, involving intensive reviews by the NHS Research Ethics Committee (REC) and regulatory checks, refined the approval process, precluding the need for multiple assessments across NHS bodies. Achieving HRA consent necessitated adherence to confidentiality protocols and the submission of extensive documentation. Only upon securing all requisite regulatory approvals could the project proceed, highlighting the essentiality of proficient project management and strategic communication. The study's outcomes shed light on AMS practices, the shifts in antibiotic prescribing patterns, and the pandemic's influence on these dynamics. Crucially, the investigation emphasised the vital importance of robust AMS in managing antibiotic utilisation and in combating antimicrobial resistance. Reflecting on this journey emphasises the importance of involving the public and patients, creating effective participant information sheets (PIS), registering research projects in databases, such as ISRCTN and OCTOPUS, and constructively addressing feedback. These lessons has significantly enhanced the authors' research skills, emphasising the crucial importance of ethical consideration and transparent communication in academic research. This article offers a thorough reflection of the Health Research Authority approval process, advocating its adoption in future antimicrobial stewardship and antimicrobial resistance investigations, which are imperative to global health. Moreover, undertaking a SWOT analysis has yielded strategic insights, facilitating a more informed approach to the process of the HRA approval process, especially in relation to COVID-19 antimicrobial stewardship research within UK secondary care.

Introduction

The journey in securing Health Research Authority (HRA) approval for a research project at One English NHS Foundation Trust was a defining experience in my academic career (1). This project comprised two studies: a retrospective review of NHS patient records and a prospective survey questionnaire of healthcare professionals at the Trust. Navigating the application process via the Integrated Research Application System (IRAS) was initially daunting, but the system's user-friendly design, which included auto-population of relevant fields and an average completion length of about 20 pages, made it manageable (2). This article's objective is to delve into the lessons learned from navigating the HRA ethical application process, coupled with a reflective analysis using the SWOT model. The project entailed a retrospective review of NHS patient records and a forward-looking survey among healthcare professionals, offering profound insights. These experiences are integral to the 'Think Ethics' initiative, advocating the value of strategic evaluation in the realm of research.

Methods

In this study, the Health Research Authority (HRA) approval process was meticulously followed, involving an extensive review by the NHS Research Ethics Committee (REC) and regulatory compliance and governance checks by HRA staff. This procedure replaced the necessity for multiple reviews by various NHS organisations, thus streamlining the focus of their study delivery capabilities (3). Central to gaining HRA approval, especially due to the requirement of accessing confidential patient information without consent, was a stringent adherence to the Confidentiality Advisory Group (CAG) application guidelines. This involved submitting a cover letter, a signed application form, the research protocol, data protection registration, and a Caldicott Guardian endorsement, with the approval contingent on both HRA and REC endorsements. The REC application played a vital role in ensuring the protection of participant rights and dignity. This necessitated a comprehensive submission of documents through the Integrated Research Application System (IRAS), including the research protocol and participant information sheets. The REC's evaluation process encompassed either full committee reviews or streamlined proportionate reviews, each with a designated timeframe. The process for booking a REC meeting via IRAS was clearly guided and straightforward. Following the booking, the REC Manager assessed the application's validity and issued a validation letter. The REC meeting provided a platform to address any ethical concerns with the committee directly (4–6). Additionally, the SWOT analysis model was employed to provide a reflective analysis of the various aspects of this process, enhancing our understanding of the operational, ethical, and practical dynamics involved in securing HRA approval.

Results

After receiving the REC's favourable opinion, it was crucial not to start the research until all regulatory approvals were in place. The study had to commence within 12 months of approval, and any significant amendments required re-approval. The SWOT analysis of the Health Research Authority (HRA) Approval Process for the Antimicrobial Stewardship NHS Research Project revealed distinct strengths, weaknesses, opportunities, and threats. Strengths included the user-friendly IRAS interface, HRA's consolidation of reviews, REC's upholding of ethical standards, and the visibility boost from ISRCTN and OCTOPUS registrations (7, 8). Weaknesses were identified as the intimidating complexity of the HRA process, the demanding nature of detailed applications, and the resource-heavy management of CAG and REC communications. Opportunities emerged from ethical feedback enhancing research design, while threats involved REC delays potentially disrupting schedules and the risks associated with continuous CAG approval reliance. The streamlined ethical approval process facilitated the development of robust studies, such as the descriptive study on the WHO AWaRe classification for antibiotic stewardship in addressing antimicrobial resistance at an English NHS Foundation Trust before and during the COVID-19 pandemic (10). Another pivotal study evaluated the 'Five Rights' of antibiotic safety at the same NHS Foundation Trust during the aforementioned periods (11). Furthermore, research findings have been shared in a poster presentation at the Royal Pharmaceutical Society and subsequently published in the International Journal of Pharmacy Practice (12). Further work includes an ongoing publication titled "Start Smart, Then Focus: Antimicrobial Stewardship Practice at One NHS Foundation Trust in England Before and During the COVID-19 Pandemic" (13), along with other forthcoming articles.

Discussion

The SWOT analysis advocates the HRA's pivotal role during the COVID-19 pandemic, facilitating the research project approvals essential for rapid vaccine development and other medical interventions. Despite strengths like the user-friendly IRAS and the efficient review consolidation, the complexity of the HRA process and the intensive resource demands for CAG and REC communications are areas that could benefit from the new ways of working, as suggested by the public involvement. Committee feedback highlights the value of diverse perspectives and structured discussions, which aligns with identified opportunities for enhancing research design through ethical feedback. Addressing the consistency of information and improving discussion frameworks could further streamline the ethics review process, potentially mitigating the threats posed by delays and continuous approval dependencies. The study gathers insights from 151 UK Research Ethics Committee members, evaluating the effectiveness of ethics reviews for rapid COVID-19 medical interventions. Emphasising the importance of diverse input and structured discussions, it identifies the need for more consistent information and clear guidance on key issues as areas for improvement (9).

Conclusion

The HRA application process, guided by the 'Think Ethics' principle, was an enlightening journey that enhanced our research skills and project management capabilities. It advocated the necessity of extensive preparation, ethical consideration, and clear communication in research. These experiences have substantially contributed to my professional development and the quality and integrity of my research project. The lessons learned are outlined below:

1. Understanding ethics requirements, such as public and patient involvement, enriches research by ensuring relevance, enhancing study design, improving materials for clarity, and fostering ethical standards that resonate with participant needs and perspectives.
2. Developing attracting materials proved crucial for enhancing participant involvement. For instance, the strategic use of a healthcare poster significantly encouraged survey participation. Placing this poster in key areas, such as wards and staff rooms, effectively reached healthcare professionals, thereby encouraging a higher response rate to the survey.
3. Registering research in ISRCTN and OCTOPUS increases visibility, promotes transparency, aligns with international standards like WHO criteria, and facilitates global collaboration in clinical research (7).
4. Efficient project management requires effective organisation, prioritisation, and budgeting of research activities.
5. Responding to provisional or unfavourable feedback, although challenging, is essential for research enhancement. This includes a thorough review of committee comments and addressing concerns in a detailed response. Initially, this process seemed daunting, but it soon became evident how vital it was for upholding the integrity of the research.

6. Responses to the REC needed to be concise, clear, and well-referenced, addressing all requested changes.
7. Regular communication with the CAG to manage the Annual Review and Closure Form ensures timely support and the conclusion of the study. Keeping the REC updated about research progress and submitting the final report is critical for providing valuable feedback and sharing research outcomes.
8. The SWOT analysis of the HRA Approval Process, as detailed in Figure 1, evaluates internal (Strengths and Weaknesses) and external (Opportunities and Threats) factors impacting the success and integrity of this NHS research project.

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Figures

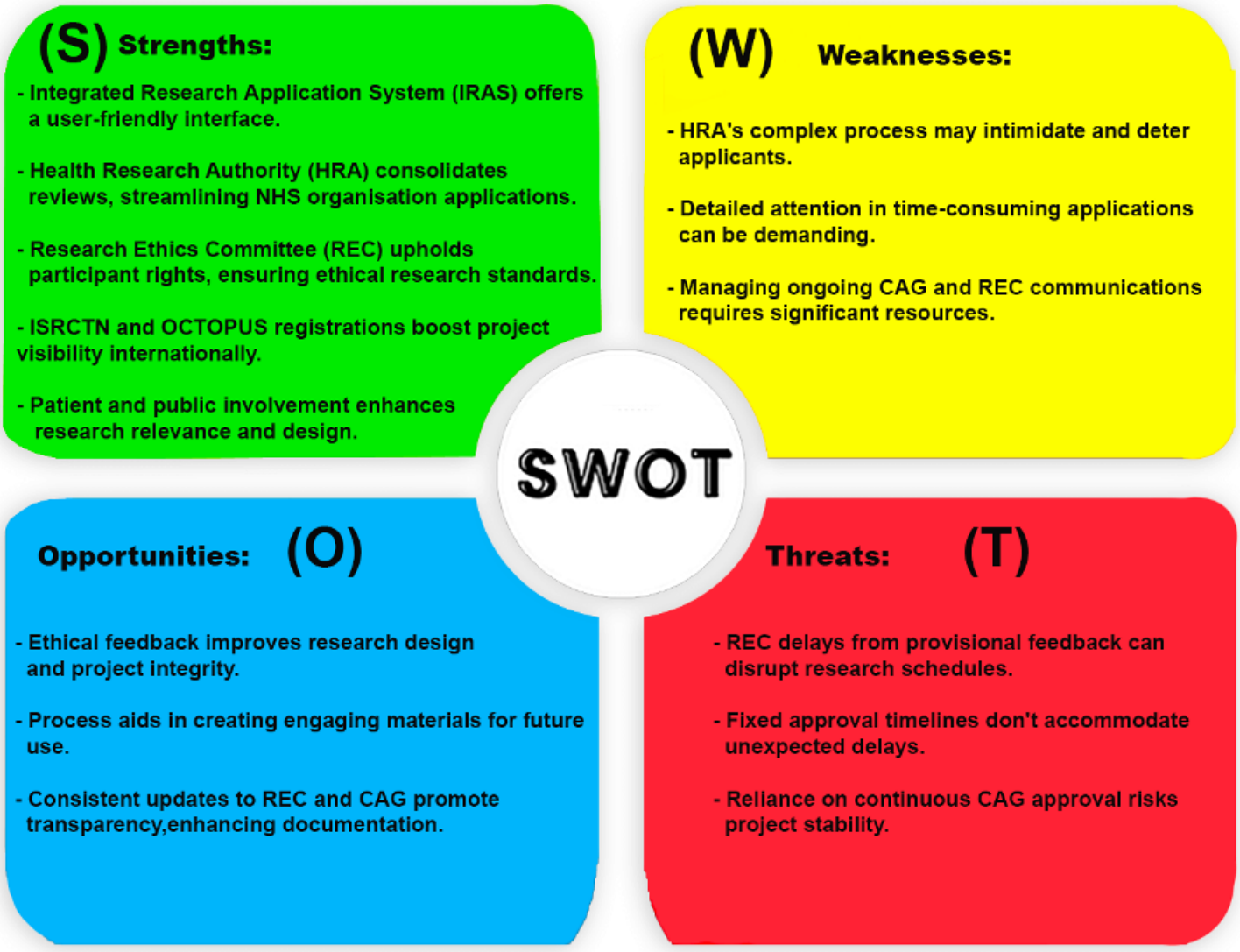

Figure 1

SWOT Analysis of the HRA Approval Process for the Antimicrobial Stewardship NHS Research Project.