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Perspectives on a Multidisciplinary Team Approach to Implementation of Planned Emergent Use Research

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In this paper we present the viewpoints of three members of a research team, on the approach to teamwork in the development of an emergent use clinical trial when dealing with diversity of opinions, in order to facilitate stakeholder buy-in. We also discuss a specific approach to the coordination of the team members, which in our opinion had a positive impact on the implementation of the project. We also comment on the influence of the team organization in the timeline and completion of a clinical trial. We hope to start a conversation on team dynamics in the design of clinical trials, especially in the context of emergent use research.

MeSH Keywords: Biomedical Research • Critical Care • Emergency Treatment • Research Design

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Background

Clinical trials require considerable time, expense, and preparation to be completed successfully. The setting and the complexity of a clinical trial may lead to the involvement of several different healthcare professionals working together towards its success. It is possible that the fast pace, severity of illness, and urgency of treatment may add further complexity to any research project. In this setting, acquiring "buy-in" from relevant critical care personnel would be paramount to effectively perform a clinical trial within this setting. This "buy-in" is an often overlooked but extremely important requirement in clinical research [1].

For clinical trials conducted under the tenants of emergent research, obtaining this form of engagement from stakeholders can be as important as the science behind the trial itself. The term "emergent research" or specifically the "exception from informed consent requirements for emergency research" refers to investigations that "involve human subjects who have a life-threatening medical condition that necessitates urgent intervention (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g., traumatic brain injury) cannot provide informed consent"[2]. We will refer to this kind of study as "emergent research" and "planned emergent use research" throughout this document.

In these cases, if informed consent is not obtained prospectively, it can be deferred as long as the principles of emergent research are met in accordance with regulatory and institutional policies [2]. The ethical implications of these exceptions can raise concerns among healthcare providers who are stakeholders in the study but lack experience on emergent research. This in turn makes enrollment in the trial under emergent research even more dependent on the stakeholder's "buy-in" than in most other investigational situations. For example, under the informed consent pathway, time is available for study personnel (e.g., study coordinator) to discuss with both the patient and the clinical team prior to enrollment. The study coordinator is knowledgeable about the research and has buy-in from the beginning. In contrast, when research is conducted under exception from informed consent, the clinical team essentially takes on the role of the study coordinator, screening patients and enrolling them when eligible. Thus, knowledge of the trial and buy-in are of utmost importance. Of note, the current article is not a discussion on the ethical and/or regulatory issues involved in critical care research. This has been published previously [3].

With this in mind, we will illustrate an example of an upcoming clinical research trial, "Ketamine/Propofol Admixture "Ketofol" at Induction in the Critically Ill Against Etomidate: KEEP PACE Trial", that will be conducted in the critical care setting under emergent use research, and how buy-in from relevant stakeholders was achieved in the phases of study implementation. This example will be viewed from the perspective of three different team members, each serving a different role on the research team.

Principal Investigator's Viewpoint: Research Team Compartmentalization and Stakeholder Buy-In

The clinical trial example involves a comparison of two different medications used for sedation in rapid sequence endotracheal intubation, and was drafted under planned emergent use research given the urgent nature of the procedure. The proposed trial was drafted by critical care physicians with no initial input from regulatory specialists, bio-ethicists, pharmacist, critical care nurses, or respiratory therapists. It became abundantly clear that conducting the study with investigators not experienced in the area of emergent use research would likely result in a protracted process and yield poor recruitment or, worse yet, no recruitment at all. By sub-dividing the clinical trial into its component parts (e.g., regulatory division, pharmacy division, ethics division) and empowering each member of their respective unit to take the "lead", the design and implementation phase ran more efficiently. This was reflected for us both in terms of financial cost and time investment. Although this "compartmentalization" concept makes practical sense in clinical medicine, little evidence exists for clinical research carried out in this fashion.

The concept of dividing a project into its component parts, by means of choreographed teams collaborating together as a whole is not new, and is currently most associated with the aviation industry from which medicine has adopted paradigms of safety (e.g., checklists and bundles) [4,5], teamwork [6], and quality measurements [7,8]. It is a common model in this industry that the respective components of the aircraft are manufactured by separate specialized teams under section leadership but with the completed aircraft always as the goal in sight. The teams then come together for collaboration on the aircraft as a whole under the coordination of the company's lead engineering team. It is common to have entire sections of the aircraft be produced in a different region of the country prior to coming together for the final result. An example of this is the manufacturing of the 320 and 350 families of Airbus aircrafts. In Germany, the Bremen site is responsible for the high-lift systems of the wings. The wings themselves are crafted in Broughton, in the United Kingdom. The plant at Stade in Germany crafts the vertical tail planes, while all the electronic communication and cabin systems are designed and produced in Buxtehude, Germany. Finally, the Hamburg site designs and manufactures fuselage sections, and is in charge of final assembly of the plane [9].

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As noted, the final result is a precisely crafted aircraft that, by all accounts, was produced by a single coordinated team that worked in specialized sections. Replicating similar examples from the aviation or automotive industry is now being done in many quality improvement programs across the United States. However, translation of the compartmentalization approach to clinical research has yet to, if you will, "take-off". The reasons remain unclear but may relate to ownership of the proposed idea, difficulties working with multiple personalities, lack of agreement among a large group of people, or the perception of losing control over the direction of the project. In our case this approach resulted in greater motivation for involvement by relevant stakeholders, as well as faster progress with less effort.

Compartmentalizing the proposed clinical trial allowed swift approval from the Food and Drug Administration (FDA) with exceptions from informed consent for emergent use research (2 months). Without the respective regulatory division that was led by an investigator experienced with FDA regulations, this process would have significantly delayed trial progress and its approval. As an example, utilizing research personnel not experienced with regulatory affairs took closer to 5 months on a prior project that was not performed under the tenets of emergent use research. Moreover, the cost was substantially reduced because a study coordinator, who likely is not experienced in this matter, would require additional time (e.g., 3 months or more) with a salary of approximately $70,000/year [personnel communication]. Alternatively, assigning this task to clinical personnel experienced in such matters, the financial burden is substantially less. After this, we then formed a section with our bio-ethicist to assist with community consultation and public notification strategies per the requirements of emergent use research. During this process, the clinical trial was presented at a medical unit management meeting with critical care charge nurses, intensive care unit pharmacists, unit respiratory therapists, and critical care intensivists. After the meeting, the research team was informed that the proposed clinical trial was not fully supported by relevant stakeholders. When questioned about the reasons for resistance, the following were cited: 1) a sense of dictatorship by the research team; 2) having no sense of responsibility; 3) concerns with additional tasks and; 4) concerns regarding scope of practice.

We realized that by splitting the clinical trial even further into additional components (e.g., nursing section, respiratory therapy section, and publicity) and empowering the members, we would create a sense of personal involvement (i.e., "buy-in") in the project. Each section was then treated with unique relevance that was perceived by the members of the team. In turn, the team members felt as if their contribution was uniquely important, which ultimately led to increased commitment and efficiency. When asking for information and empowering them with the protocol, these relevant stakeholders were more likely to support the proposed clinical trial. Furthermore, they were more likely to achieve buy-in from their respective divisions with the view that they shared the same high stakes. More importantly, relevant stakeholders were able to add modifications to the protocol and planned procedures that were more in-line with what was the standard of care when performing their tasks. Empowering the team members allowed opportunities to advise on certain elements under their expertise in order to have buy-in with the rest of the members on their team. For example, the nursing manager advised the investigators on how to implement the mixing of study medications in a way that staff nurses would be comfortable with. By compartmentalizing the clinical trial, sense of ownership and clinical trial progress increased significantly (only 3 months to overcome all logistical hurdles and submission to IRB, as compared to 8 months in a clinical trial of similar complexity [personnel communication]). Likewise, financial costs were much lower than if several study coordinators/research assistants were assigned to each section (essentially no extra charge for empowering already paid staff to develop a protocol that "fits" their needs *vs.* roughly $70,000 per study coordinator). In the end, the respective divisions included: Regulatory, Ethics, Pharmacy, Respiratory Therapy, Critical Care Nursing, and Publicity sections. All divisions had approximately three members with experience regarding the assigned tasks. Each division had a team captain who was the most experienced individual in that division, based on prior study experiences/publications. The team captain reported to the research liaison of that division, who would then communicate regularly with the principal investigator. After approval from the other investigators, the principal investigator signed off on implementation strategies (see Figure 1 for the organizational chart and study tasks). The timeline estimates noted above are important because the clinical trial discussed herein is the *first* planned emergent use research clinical trial at our institution.

The reasons stated above perhaps contribute to the paucity of literature on clinical trials conducted in a setting such as the intensive care unit when it comes to planned emergent use research. Involving additional stakeholders into the research process in an environment of physical and psychological stress increases the likelihood of successful completion. The requirement of buy-in is much easier to solve if relevant stakeholders are involved with study planning and procedures than if they are not included in this process. It is the authors' own opinion that conducting previous clinical trials without the compartmentalization approach but in a rather linear fashion (with planning events happening in sequence one after the other) adds significant time and cost to trials, as mentioned above. In conclusion, based on our experience, we feel that compartmentalizing the implementation of a clinical trial improves team dynamics and commitment with efficient trial progress,

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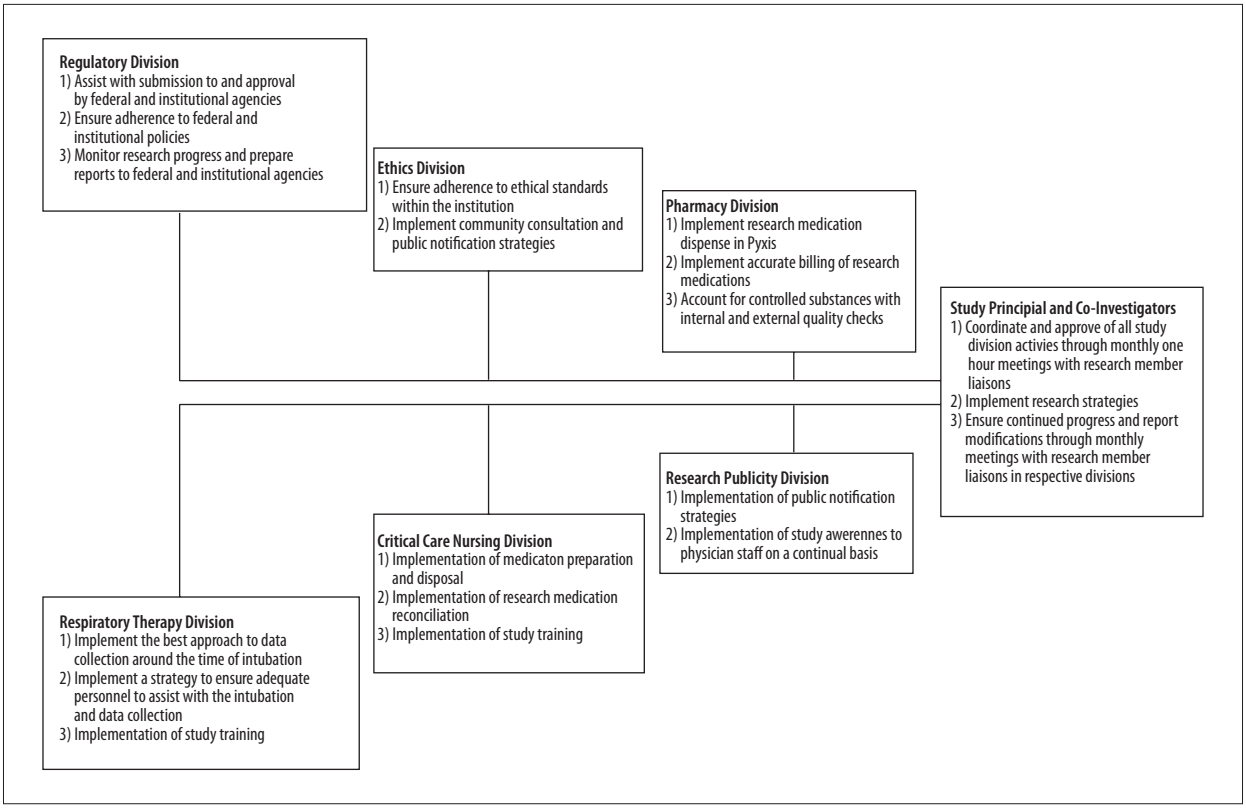

Figure 1. Organizational flow chart of study sections and tasks within each section.

and may reduce costs. The increase in stakeholder buy-in is useful when involving critical care patients in planned emergent use research.

Nursing Liaison Member Viewpoint: The Perils of Multidisciplinary Interaction in Research

For a clinical trial to be successful, it is necessary that several healthcare professionals work together towards the same goal. While this seems a logical approach, particularly in the critical care setting where we are fast evolving towards a multidisciplinary team approach [6,10], it is harder to achieve than might be imagined. The nursing section leadership of the investigative team learned of this difficulty after joining the critical trial team as the liaison with nursing personnel. From the first meeting with the nursing staff, we noticed that we had in common our desire to work for the patient's best interest. However, we also realized that our desire to achieve the patient's best interest differed significantly in our approach, intermediate goals, and general points of view [11,12].

Nurses are foundational to all fields of medicine and this is most true in critical care. Most nurses hone their skills and put them into practice with standard operation protocols, checklists, and experience to develop greater nursing diagnostic acumen. The training of critical care physicians tends to emphasize identification of a problem and decision making in the role of team leader. While the lines separating the practice methodology between physicians and nurses have overlapped in recent years (especially with protocols and checklists), there still appear to be differences in the approach to care. These discrepant philosophies between nurses and physicians have been the subject of several papers, particularly in the nursing literature [11,13–15]. This led to situations of contrast of opinion regarding the design and preparation of the protocol, as well as its implementation. While the medical investigative team wanted a protocol designed to be brief and streamlined, nursing personnel seemed to favor a protocol with greater degree of detail and a step-by-step guide. Whether this is reflective of the prior training paradigms as noted above is an interesting question.

It became clear to both parties that open communication and understanding of their distinct points of view would be the key to the success of our partnership. It was the section leader's responsibility as nursing liaison to ask many questions and answer many more in an effort to understand and address all of their concerns regarding their role in the new clinical trial. In the end, we adapted our distinct ideas to fit each other's needs, especially for the nurses to channel their participation in the trial through the scope of their prior training.

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For example, in the ICUs where the trial is recruiting, we have well-established protocols and checklists to review at the moment of intubation. Despite the above, we sensed a high level of concern from the nursing staff that enrolling patients during intubation would complicate a process that was safe and working effectively. Therefore, we agreed on how we could add the clinical trial protocol to daily practice without jeopardizing patient care and safety. As a team, we decided to create online educational material consisting of a PowerPoint presentation and videos illustrating how to prepare the admixture of ketamine and propofol. Additionally, we placed copies of all the nursing forms in every room of the units where patients can be recruited. We also recognized that both roles were equally important in ensuring appropriate patient care without compromising the clinical investigation.

Another area of divergence of opinions among all the stakeholders in the project is the fact that it will be conducted under an emergent use research model, a concept often difficult to effectively convey. The subjects involved in emergent research are usually very ill, in critical life-threatening conditions. Their acute state requires prompt action, where taking time to obtain consent is often impossible due to altered mental status or poor judgment while in distress. Also, taking time to locate family members or legal representatives may lead to an unfavorable outcome. In these cases, providers work under principles of non-maleficence, beneficence, and justice, towards the patient's best interest [16,17]. Considering the lack of autonomy of the critically ill patient and their inherent vulnerability, it was understandably difficult to make the nursing staff and ancillary personnel accept the idea of not asking for direct informed consent for intubation or medication. The provisions and exceptions for emergent use research outlined by the United States Food and Drug Administration were carefully outlined and explained to all stakeholders in an effort to develop greater comfort with the concept of investigational drug use in the acute situation. Once concerns of violation of patient autonomy and safety were dissipated, all parties came to an agreement on how to best proceed with the nursing role in the project.

In the end, it is clear that in investigation, as elsewhere in life, a little humility goes a long way. Humility to realize that there is a lot to be learned from others, and to understand that assumptions are often counterproductive. It is not unusual to have conflict of ideas when one is involved in healthcare, whether it is at the bedside or in the design of a clinical trial. When working in a team of people with different backgrounds, it is imperative to develop an understanding of each member's current position. Ask questions and be ready to answer many more. Along those lines, critically appraise your answers and perhaps most important of all, don't take anything personally. If you take a step back, you will soon realize that we are all in this for a common greater goal: Our patients' wellbeing and groundbreaking research.

Physician Section Member Viewpoint: The "Pit-Crews Model" in Clinical Research

The scientific method has been fundamental for much advancement in modern human history. Indeed, experimentation has led to the current progress of science and technology in society at least since the seventeenth century. Medicine is not alien to this, and scientific trials both on basic and clinical science are the reason why modern medicine has tools to treat a wide array of human afflictions. In order to be effective in obtaining the information needed for these advancements, clinical trials are carefully planned and designed. This carries inherent difficulties, which can only be solved through strict organization and coordination of the many steps necessary to carry out such trials.

As long as a trial is sensibly designed and effectively implemented, we may consider using the results to update our clinical practice, which highlights the relevance of properly conducting these studies. This translates into a complex and long multi-step process with several variables, often spending many months in the planning stage. This may intimidate many clinicians with respect to participating in research, especially during their training years [18,19].

With the growing complexity of modern medicine, it has been postulated that healthcare providers in general (physicians, nurses, physician assistants, and other personnel) can no longer be "lone rangers" in the battle against disease. A multidisciplinary approach has been advocated more and more in recent years by a growing body of literature, and has been associated with improved outcomes [10]. Furthermore, the example from other industries, such as the aviation and automobile industries, has been adapted to clinical practice in an effort to achieve quality control in the delivery of healthcare. Of special interest has been the use of coordinated, even synchronized, efforts as a team to achieve an otherwise complex goal with minimal risk of error and excellent quality. The use of checklists in particular has been touted and adopted as a method to ensure the delivery of complex protocols of care in an attempt to increase efficiency and reduce errors. This was made most popular by Dr. Atul Gawande in his book, "*The Checklist Manifesto*" and has been adopted in intensive care units and operating rooms throughout the United States [4].

A recent analogy running along these lines in the medical quality press is that of imitation of "Pit Crews" to improve healthcare in the United States [20]. Choreographed pit crews came to be in 1963 in the Daytona 500 Series car races, and in the modern era the structure of a pit crew differs slightly among Formula 1, NASCAR, or Endurance Racing teams, but it has common roles: A crew chief, one or two jack-men, a group of tire changers, a group of tire carriers, a gas man, and a "seventh

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man" who caters to the driver, providing drinking fluids and wiping the helmet and windshield. Their many rehearsals and deep understanding of their role in the maintenance of the vehicle allows them to service the car and the driver both efficiently and effectively in a minimal amount of time, thus increasing the chances of victory for the team. More than their speed, it is their organization and coordination towards a common goal that is argued to be used as a model for the delivery of care in many hospitals.

It is interesting how this model seems to not have widely permeated into clinical research, or at least not in a more visible fashion. The body of literature on team dynamics and coordination is fairly small, so the best approach to coordinate a research team within clinical medicine is either not known or not published, at least not in intensive care [21,22]. In planning and implementing an upcoming clinical trial, we utilized the approach described in the paragraph above: one of compartmentalization, similar to that of a pit crew. The tasks of the trial were split among a group of individuals who developed an in-depth understanding of their particular roles on the team. This increased the sense of ownership of their task as an important part of the study, all under a lead coordinator (the "crew chief" or principal investigator in the current paper). Each subunit worked as one and reported to the principal investigator both achievements and hindrances on a weekly basis. As such, a regulatory section, pharmacy section, ethics section, public relations and media section, nursing section, and respiratory therapy section were developed. Instead of a "linear approach", we worked in a centripetal fashion towards a common core: **The implementation of protocol design and initiation of enrollment in an effective and efficient fashion and in the shortest time possible.**

In our opinion, this had several positive consequences:

1. A sense of importance of one's role within the team. This feeling of relevance and of being indispensable fosters intensity of work and a commitment to what one does [23].
2. A greater focus on one's task improves quality of work, however complex the task may be.
3. A completion of the whole in an expeditious fashion while maintaining a high standard of the product. Similar to how a pit crew can service a race car in seconds, our team managed to implement the clinical trial in a few months, when it could have taken almost a year for a randomized controlled trial of this nature (emergent use research).

As an example of the above, the physicians on the team had challenges in the implementation of the trial because the message conveyed by them to the other stake-holders was viewed as alienating. The physician team members approached the research as they would any other study, as a linear process with multiple steps that were ill-defined in particular areas such as regulatory, ethics, and nursing. When the physician members were assigned to help with individual tasks, they gained a deeper understanding of the component parts. In turn, communication and understanding of trial implementation within the different areas increased significantly, ultimately leading to higher-quality and more efficient research.

A model similar to this, or to the ones already mentioned above (aviation and car industries), appears effective in stimulating the advancement of clinical research with complex protocols in a relatively short period of time. It instills all members of the team with a deep sense of involvement in the project and increases personal satisfaction, which seems to increase productivity. The synchronicity of tasks increases efficiency and effectiveness, and as long as there is communication with a leader, the results are homogeneous. It is the opinion of our team that this is an excellent and rather underused approach to the implementation of clinical research protocols, and it should be analyzed in greater depth.

Conclusions

It was our goal with this paper to add to the conversation on multidisciplinary approach to clinical investigation, particularly in the setting of emergent use research. Notably, the literature is scant with regards to team roles, collaboration, and dynamics in clinical research in medicine. We are especially interested in team organization, member interaction, and the impact that this has on goal achievement.

We seek to highlight the approach we took in the initial implementation of an upcoming clinical trial with a focus on our particular perspectives regarding the organization and roles of our team, with special interest in the strategy of compartmentalization of work, as well as how taking into account the background of the members of the team and their scope to healthcare in general on the basis of the nature of their training can enhance the quality of the interaction among the members of the team. Our team dynamic strategies are in accordance with strategies for effective teamwork described in the available literature, [24] which, as we mentioned before, is not abundant.

We hope there will be a greater interest in adding to the literature on team organization, team interaction, and implementation of clinical trials in the intensive care unit, especially all associated with the concept of emergent use research, which we feel is a changing paradigm in the future of investigation in critical care medicine.

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