

# Pragmatic trials are needed to assess the effectiveness of enhanced recovery after surgery protocols on patient safety

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Contemporary healthcare systems comprise a myriad of organisations and professionals committed to patient care. These systems often develop innovations that are not easily transferable from one context to another. Three decades ago, Enhanced Recovery After Surgery (ERAS) protocols originated in Northern Europe, introducing a systematic approach to perioperative care, initially focusing on major colorectal surgeries.<sup>1 2</sup> Using a patient-centred and evidence-based approach, their goal was to improve patient's early recovery through enhancing the quality of surgical processes. ERAS protocols were specifically designed to facilitate the dissemination of multimodal perioperative care pathways covering all aspects of the patient's surgical journey. Addressing key factors traditionally extending post-surgery hospital stays, including the need for analgesia, intravenous fluids due to gut dysfunction and bed rest due to limited mobility, the ERAS protocols offered guidance for well-coordinated perioperative care teams.<sup>3</sup> These protocols have since transcended borders, catalysing transformative changes in healthcare organisations globally across multiple surgical fields.<sup>4 5</sup> Aiming for consistent quality across diverse healthcare systems, ERAS protocols allow the replication of standardised strategies within the unique contexts of each surgical department, thereby fostering their adaptation and improvement. The expected effectiveness of ERAS protocols in facilitating upscaling across diverse healthcare environments stems from their evidence-based foundation, comprehensive coverage, flexibility for different surgical procedures and

patient populations, clear guidelines and emphasis on multidisciplinary collaboration. Focused on scientifically proven best practices, ERAS protocols also undergo periodic updates. Successful ERAS implementation typically involves participating in an education programme to form a multidisciplinary team with members from diverse perioperative care units and conducting regular meetings to discuss care processes and clinical outcomes. Additionally, audit and feedback plays a dynamic and integral role in ERAS implementation, aiding in monitoring adherence to guidelines, identifying improvement areas, and fostering team collaboration.<sup>3</sup>

Previous research has centred on the efficacy of ERAS protocols. Explanatory clinical trials, using individual patient randomisation, have demonstrated a notable reduction in both postoperative complications and length of stay, although the impact on overall mortality and readmission rates remains uncertain.<sup>6 7</sup> Hospitals' adherence to enhanced recovery criteria has also been associated with lower postoperative complications among patients undergoing elective colorectal surgery.<sup>8</sup> However, evidence regarding the effectiveness of ERAS protocols in real-world settings from pragmatic trials has been lacking to date.<sup>9</sup> The paper by Pagano<sup>10</sup> in this issue of *BMJ Quality and Safety* therefore offers valuable insights to address this knowledge gap, informing decisions on the widespread adoption of complex interventions such as ERAS protocols. The authors conducted a stepped-wedge cluster-randomised trial to evaluate the impact of implementing enhanced recovery after colorectal cancer

surgery within a regional hospital network in Italy, supported by audit and feedback.

This well-designed study imparts valuable lessons grounded in a high level of scientific evidence.<sup>10</sup> As might be anticipated, the routine introduction of the protocol into surgical care resulted in higher compliance with many ERAS process quality criteria (eg, preadmission counselling, preoperative nutritional risk assessment and carbohydrate loading, postoperative early re-feeding and mobilisation), accompanied by a reduction in the length of inpatient stays. Such adoption of the protocol by surgical departments had the potential to enhance consistency in the quality of surgical care provided to the population within the hospital network. To achieve this, successful ERAS implementation within each surgical department required important additional features to overcome resistance and reshape existing surgical processes in diverse healthcare environments. As with any complex intervention, bundling features with distinctive mechanisms of action was intended to have synergistic effects.<sup>11</sup> The first feature involved the identification and commitment of a dedicated interprofessional team trained to install ERAS multimodal and multidisciplinary approaches in each centre. The second feature entailed an audit and feedback strategy to assess both process compliance and patient outcomes. Thus, the approach taken by Pagano exemplifies a comprehensive approach to teamwork and continuous data-driven support, fostering cultural and organisational change. As is common with bundled interventions, this does, however, raise the question of the real effect attributable to compliance with the ERAS process quality criteria alone, independently from other intervention components. Because engagement with audit and feedback was not reported, we cannot disentangle which elements of the bundle are most important to reproduce the intervention's impact.

Previous explanatory clinical trials demonstrated the theoretical benefits of ERAS protocols in reducing postoperative complications among patients undergoing colorectal procedures.<sup>6</sup> However, these benefits do not necessarily replicate in a real-world scenario. In the present pragmatic trial, no beneficial impact on clinical outcomes was observed. Instead, there was a non-significant trend toward a higher risk of complications, reoperations, deaths or hospital readmissions in patients exposed to ERAS protocols.<sup>10</sup> This raises questions about the safety of ERAS protocols in practice and prompts hesitations regarding their broader adoption across all surgical departments. A plausible explanation for these results, as presented by Pagano, may be linked to the limited adherence to, on average, only two-thirds of the ERAS process items in participating centres. It may be that full compliance with all of these items is necessary to anticipate benefits similar to those achieved in the highly controlled experimental framework of previous clinical trials. Another

explanation may arise from insufficient case-mix control in this pragmatic trial. An increased average complexity among patients needing surgery, coupled with limited access to critical care during periods of elevated COVID-19 hospital exposure, could have resulted in a higher risk of complications and poorer postoperative outcomes.<sup>12</sup> This methodological issue is particularly notable because participating hospitals experienced implementation of the ERAS protocol concurrently with the pandemic in 2020/2021. Moreover, the impact of ERAS was predominantly assessed in comparison to patients from pre-pandemic control periods.

Pagano's paper therefore provides evidence on the impact of ERAS in reducing hospital length of stay rather than improving patient clinical outcomes. The initial objective of the ERAS approach was not only to expedite recovery and reduce hospital length of stays but, more importantly, to uphold and enhance patient safety. Over time, there has been a shift in the research agenda, moving away from the original focus when evaluating ERAS. This shift replaced crucial indicators of recovery, such as complications or readmissions, with length of stay as the most commonly chosen primary criterion. The emphasis on length of stay does not align with patient-centred outcomes and could be potentially misleading, as a decreased length of stay may coincide with an increased risk of post-discharge readmission and overall healthcare costs.<sup>13</sup> A substantial decrease in the length of the index stay does not automatically translate to a reduction in overall hospital bed days and costs in the mid-term, especially if subsequent readmissions occur due to post-discharge complications stemming from inadequate patient follow-up.<sup>14</sup> Furthermore, implementation of an ERAS protocol involves a significant input cost for hospitals that must be weighed against the expected benefits associated with reduced lengths of stays. Hence, the potential gains in the efficiency of care bundles designed to enhance post-surgery recovery deserve to be demonstrated from a societal perspective, relying on a comprehensive economic assessment.

In summary, the paper by Pagano represents an important contribution, offering a pioneering pragmatic trial testing an ERAS protocol in the real world. Additional cluster-randomised trials and large quasi-experimental studies are necessary to elucidate the true impact on patient safety of implementing the enhanced recovery after surgery across healthcare systems. Emphasising the assessment of patient clinical outcomes is crucial to promote the widespread use of ERAS. Simultaneously, accurately considering time-based confounders and dissecting intervention components are essential steps to better understand their mechanisms and effects. The challenge also lies in designing impactful implementation strategies that ensure full compliance with updated ERAS criteria and encourage patient participation in their care.<sup>15</sup>

Pursuing top surgical quality targets, supported by tangible evidence, is a prerequisite that can ultimately lead to improved patient outcomes at a lower cost for the population.<sup>16</sup>

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