

IMPLEMENTING A NATIONAL, MULTICENTER PROTOCOL FOR CHILDHOOD ACUTE LYMPHOBLASTIC LEUKEMIA IN PAKISTAN WITH PROSPECTIVE, CENTRALIZED DATA COLLECTION

A Pakistan Society of Pediatric Oncology (PSPO) National Implementation Report – PSPO ALL-2020-01
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INTRODUCTION

Childhood acute lymphoblastic leukemia (ALL) is a highly curable malignancy when treatment is delivered through standardized protocols supported by reliable diagnostics, supportive care, treatment monitoring, and longitudinal follow-up. However, implementation of standardized care across low- and middle-income countries (LMICs) can be challenging because treatment practices, institutional resources, and data-collection systems may differ substantially between centers. In Pakistan, pediatric oncology care is delivered across multiple institutions with differences in clinical resources and treatment capacity. Historically, the absence of a shared national treatment protocol and centralized prospective data system limited opportunities to evaluate outcomes across institutions, identify variations in care, and generate nationally representative evidence. The Pakistan Society of Pediatric Oncology (PSPO) therefore initiated a national collaborative effort to develop and implement a standardized treatment protocol for childhood ALL accompanied by prospective multicenter data collection. The initiative was designed not only to standardize treatment, but also to establish the infrastructure required for multicenter clinical research and continuous assessment of childhood ALL outcomes in Pakistan.

Objective: To describe the development and implementation of Pakistan's first national multicenter standard-of-care protocol for childhood ALL and evaluate the feasibility of prospective, centralized data collection across participating pediatric oncology centers.

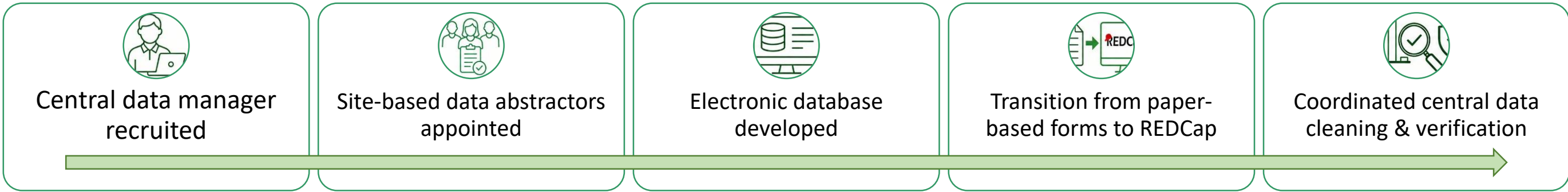


Figure 1. Data management system

RESULTS

- Governance-to-launch timeline:** Protocol development progressed over approximately 11 months from initial national concept presentation to implementation readiness. National Bioethics Committee approval was obtained within 3 months, while institutional ethics approvals were secured progressively as participating centers joined the study, enabling phased multicenter implementation from 2021 onward.
- Network reach and enrollment:** The protocol was implemented across six pediatric oncology centers nationwide, establishing Pakistan's first shared-protocol childhood ALL treatment network. Over a 44-month enrollment period (June 2021 to February 2025), 1,536 evaluable patients were enrolled, representing an estimated 14–17% of the national childhood ALL burden based on approximately 2,500–3,000 new cases annually.
- Dataset completeness and dissemination:** Centralized verification identified and excluded 124 records (7.5% of those registered) as duplicates or incomplete, yielding a final analytic cohort of 1,536 patients — a 92.5% data-verification yield; this cohort was analyzed and presented nationally at the PSPO conference in February 2026, demonstrating that the platform could support not just data collection but downstream analysis and knowledge dissemination.

DISCUSSION

- The approximately six-month combined national and institutional approval pathway demonstrates that multicenter regulatory implementation can be achieved efficiently when consensus-building and site engagement occur early. The high data-verification yield (>92%) also suggests that dedicated site abstractors and centralized data management were important contributors to data quality, particularly in a setting where routine documentation and staffing constraints can challenge multicenter data completeness.
- Several factors likely supported successful implementation. PSPO provided a national platform for coordination and shared ownership across participating centers, complemented by PSPO-hired site data abstractors and centralized data management that reduced reliance on clinical teams. Support from the GICC, followed by continued support from St. Jude, enabled development of the data infrastructure and transition to REDCap, strengthening standardized data capture, central oversight, and data-quality monitoring.
- This model aligns with three of the four WHO GICC CURE pillars: Care Network Development, Regimens for Standardized Care, and Evaluation and Monitoring. Future priorities include sustaining data-management capacity and assessing whether this governance and data model can be extended to other pediatric malignancies and centers with differing resources.

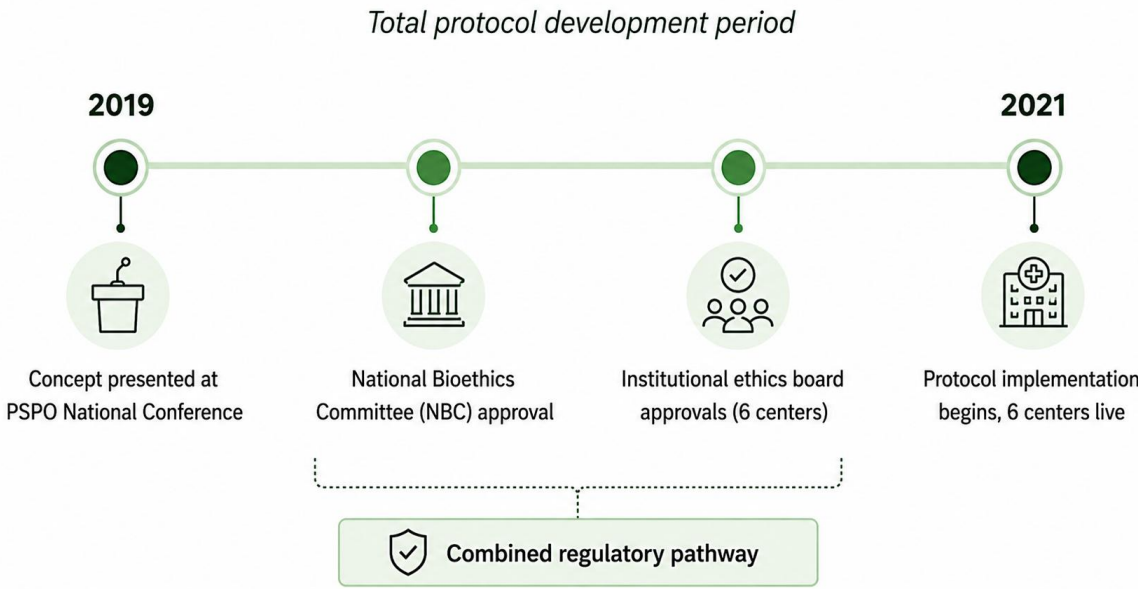
CONCLUSION

Implementing a national standardized treatment protocol with centralized, prospective data collection for childhood ALL is feasible in a resource-constrained LMIC setting. Structured governance, dedicated data infrastructure, and electronic data systems enabled large-scale multicenter collaboration. This model can serve as a template for extending standardized, data-driven care to other pediatric cancers in Pakistan and similar settings.

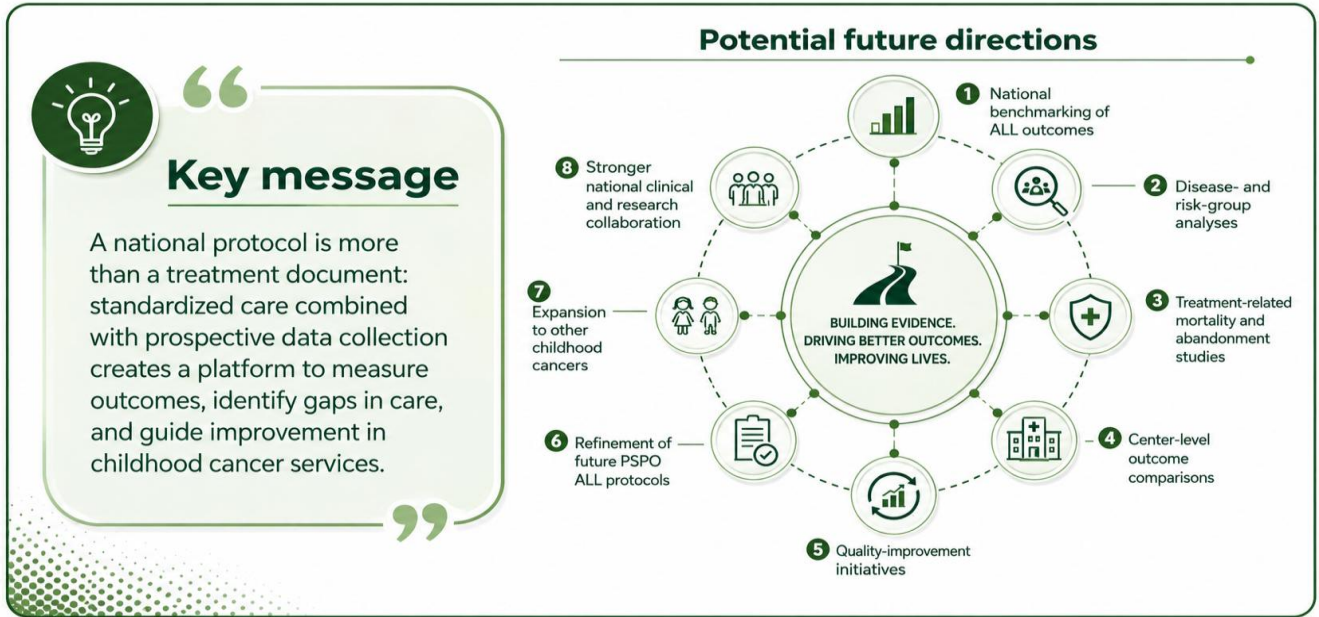
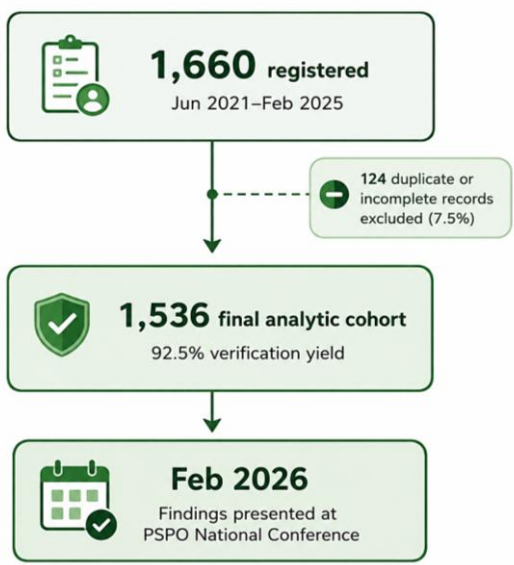
METHODS

- Descriptive implementation report** tracking process and non-clinical feasibility indicators for a national multicenter program.
- Governance & protocol design:** concept introduced at the PSPO national conference (2019). Principal investigators and national experts then convened in structured consensus meetings to design a risk-stratified treatment protocol (PSPO ALL-2020-01) and a shared, centralized data-collection framework, securing multicenter buy-in from the outset.
- Regulatory pathway:** two sequential stages — national approval from the National Bioethics Committee (NBC), followed by institution-level approval from each participating center's institutional ethics board.
- Data infrastructure:** initially, patient information was recorded using standardized paper-based case report forms. Support from a Global Initiative for Childhood Cancer (GICC) grant enabled development of a more structured national data-management system (Fig. 1).
- Rollout:** The non-randomized, standard-of-care protocol was implemented across six pediatric oncology centers in 2021, with consecutive enrollment of eligible patients continuing through February 2025.
- Feasibility indicators tracked:** time to regulatory approval, number of participating centers, cumulative enrollment, and dataset completeness/verification yield.

Governance-to-launch timeline



Enrollment, verification, and dissemination



Key message

A national protocol is more than a treatment document: standardized care combined with prospective data collection creates a platform to measure outcomes, identify gaps in care, and guide improvement in childhood cancer services.



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