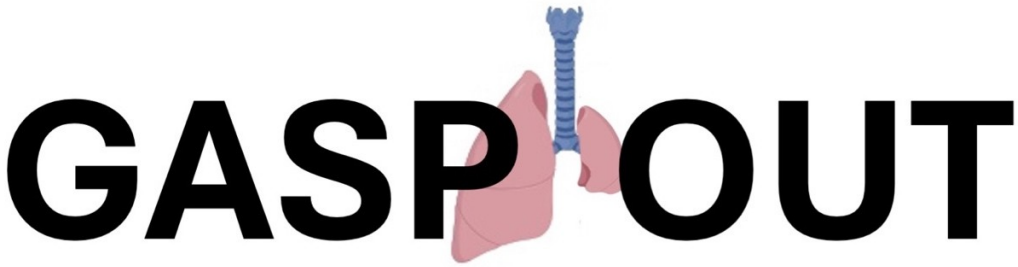
Global Assessment of Spontaneous Pneumothorax: Outcomes and Treatment



An international prospective cohort study on spontaneous pneumothorax

Study Protocol, version 1.0

6 October 2025

ISRCTN, The UK's Clinical Study Registry number for **GASPOUT_study**: **ISRCTN69084322**

ItSurg
Italian Surgical Research Group

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PROJECT TIMELINE

Phase	Activity	Duration	Approx. Months
1	Ethics approvals, site setup	3 months	Jan–Apr 2026 (0–3)
2	Recruitment of consecutive patients	6 months	May–Nov 2026 (4–9)
3	30-day follow-up and interim validation	Overlaps with recruitment	Jun–Dec 2026 (5–10)
4	12-month follow-up	12 months	Nov 2026–Nov 2027 (10–21)
5	Data lock and analysis	3 months	Jan–Mar 2028 (22–24)
6	Dissemination and reporting	12 months	Apr-Dec 2028 (25–33)

DATA COLLECTION PERIOD

Data Collection Period	Start Date (00:00)	End Date (23:59)	30-Day Follow-Up Ends (23:59)	12-Month Follow-Up Ends (23:59)
Period 1	4 May 2026	17 May 2026	16 June 2026	16 May 2027
Period 2	18 May 2026	31 May 2026	30 June 2026	30 May 2027
Period 3	1 June 2026	14 June 2026	14 July 2026	14 June 2027
Period 4	15 June 2026	28 June 2026	28 July 2026	28 June 2027
Period 5	29 June 2026	12 July 2026	11 August 2026	11 July 2027
Period 6	13 July 2026	26 July 2026	25 August 2026	25 July 2027
Period 7	27 July 2026	9 August 2026	8 September 2026	8 August 2027
Period 8	10 August 2026	23 August 2026	22 September 2026	22 August 2027
Period 9	24 August 2026	6 September 2026	6 October 2026	6 September 2027
Period 10	7 September 2026	20 September 2026	20 October 2026	20 September 2027
Period 11	21 September 2026	4 October 2026	3 November 2026	3 October 2027
Period 12	5 October 2026	18 October 2026	17 November 2026	17 October 2027
Period 13	19 October 2026	1 November 2026	1 December 2026	1 November 2027
Period 14 (Final)	2 November 2026	15 November 2026	3 December 2026	3 November 2027

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SUMMARY

BACKGROUND

Spontaneous pneumothorax (SP) is a common cause of acute chest pain and respiratory

distress in adolescents and adults, managed across emergency, medical, and surgical specialties. Despite contemporary international guidelines, substantial global variation persists in the assessment, imaging, and management of first-episode SP, particularly regarding aspiration, drain size, use of suction, and timing of surgical referral. Evaluating current practice provides an opportunity to benchmark adherence to evidence-based standards and identify gaps in emergency and surgical care delivery.

METHODOLOGY

The *Global Assessment of Spontaneous Pneumothorax: Outcomes and Treatment (GASPOUT)* study is an international, prospective, multicentre observational cohort study. Consecutive patients of any age presenting with spontaneous pneumothorax will be included, stratified by age group (<18 years and ≥18 years). Participating sites will collect data prospectively using a standardized electronic case report form during predefined 14-day data collection windows over a 6-month recruitment period. Each patient will be followed up at 30 days and 12 months to record recurrence, further intervention, and outcomes. No changes will be made to routine care pathways. A mandatory site survey will capture hospital resources, guideline use, and access to thoracic surgery.

DISCUSSION

GASPOUT will provide the first global dataset describing contemporary management of spontaneous pneumothorax across paediatric and adult populations. It will identify variability in adherence to international guidelines, quantify differences in management between specialties and healthcare settings, and describe short- and long-term outcomes. These results will inform international consensus, guide implementation strategies, and ultimately improve quality and equity of care for patients with spontaneous pneumothorax worldwide.

BACKGROUND

INTRODUCTION

Spontaneous pneumothorax (SP) most commonly presents in adolescence and young adulthood and represents a spectrum ranging from isolated, self-resolving air leak to life-threatening cardiorespiratory compromise. International expert societies and recent guideline efforts have moved away from size-based algorithms alone toward a symptom- and stability-driven approach to initial management, emphasizing clinical assessment when selecting observation, aspiration, small-bore drainage, or chest tube insertion (1, 2).

Pediatric-focused evidence and consensus statements reinforce this symptom-guided philosophy for adolescents, recommending observation for minimally symptomatic patients and favouring needle aspiration or small-bore (pigtail) catheter drainage as safe first-line interventions in many cases. Routine cross-sectional imaging (CT) is not recommended for every patient and should be reserved for selected situations (for example, suspected underlying structural lung disease, atypical presentation, or pre-operative planning). These pediatric recommendations are consistent with systematic reviews that show no clear benefit of routine CT for predicting recurrence and that suggest early operative referral may be appropriate for ongoing air leak (3, 4).

Randomized trials and meta-analyses comparing needle aspiration with tube thoracostomy in symptomatic primary spontaneous pneumothorax report similar success and recurrence rates but indicate that aspiration is associated with fewer procedure-related complications and shorter hospital stays in many series. Consequently, contemporary adult and pediatric guidance increasingly supports a trial of aspiration or small-bore drainage in suitable patients, with escalation to tube thoracostomy or surgical management when aspiration fails or when a persistent air leak develops (5, 6).

Despite these converging recommendations, substantial international variation persists in initial management decisions (aspiration vs drainage vs ambulatory management vs early surgery), device choice and size, use of suction, and timing of surgical referral, all of which may influence both short-term outcomes (time to re-expansion, complications, length of stay) and long-term outcomes (recurrence, need for definitive pleurodesis). High-risk patient groups (for example, those with Marfan syndrome, Birt-Hogg-Dubé, lymphangioleiomyomatosis, cystic fibrosis, or alpha-1 antitrypsin deficiency) require explicit

identification because they have different natural histories and management considerations (2, 4).

A multicentre, global prospective study that stratifies analysis into pediatric (<18 years) and adult (≥18 years) cohorts will quantify adherence to contemporary guideline-derived audit standards, describe real-world practice variation (including device selection, aspiration attempts, suction use, and surgical timing), and measure both short- and longer-term outcomes. Such data are essential to identify evidence gaps, inform future guideline refinements, and support implementation strategies tailored to age groups and resource settings (1, 2).

Surgical management: Persistent air leak (>48–72 hours) or recurrent pneumothorax often necessitates surgical intervention. Video-assisted thoracoscopic surgery (VATS) is the most widely used minimally invasive approach, offering reduced postoperative pain, shorter hospital stay, and low recurrence rates compared with open thoracotomy. Techniques include bullectomy/bleb resection and pleurodesis (mechanical or chemical). Robotic-assisted thoracic surgery (RATS) is increasingly reported but remains less common. The choice of approach (VATS, open, robotic, or hybrid) and technique is influenced by patient age, comorbidities, anatomical considerations, and local surgical expertise. Recording these procedural details is critical for evaluating guideline adherence and outcomes across centers.

STUDY AIMS

Primary objective:

To evaluate, in a global prospective cohort, adherence to international guideline-derived audit standards in the assessment, initial management, and early follow-up of first-episode spontaneous pneumothorax among pediatric (<18 years) and adult (≥18 years) patients.

Secondary objectives:

1. <u>Management strategies and processes</u>
    - Describe international variation in first-line management (observation, aspiration, small-bore drainage, large-bore drainage, ambulatory management, immediate surgery).
    - Quantify use of diagnostic imaging (CXR, CT, ultrasound) and adherence to guideline recommendations (e.g., avoidance of routine CT).

- Assess patterns of chest drain management (drain size, use of suction, timing of removal).

2. Short-term clinical outcomes
    - Time to lung re-expansion (radiographic or clinical or echographic).
    - Incidence and duration of persistent air leak (>48–72h).
    - Complications: infection, bleeding, device displacement, re-expansion pulmonary edema, anaesthesia/sedation events (especially in adolescents).
    - Length of hospital stay (LOS) and 30-day readmission rates.
    - 30-day mortality (rare in SP but relevant).
3. Long-term outcomes
    - Recurrence rates at 6 and 12 months (ipsilateral and contralateral).
    - Need for definitive intervention (VATS, pleurodesis, thoracotomy).
    - Return to baseline activity (school, work, sport).
    - Patient-reported outcomes (optional): pain, satisfaction, quality of life.
4. Predictors and risk factors
    - Patient-level predictors of poor outcomes, including comorbidities and genetic syndromes (Marfan, Birt-Hogg-Dubé, Ehlers-Danlos syndrome, Cystic Fibrosis, Lymphangioleiomyomatosis/Tuberous sclerosis complex, alpha-1 antitripsin deficiency).
    - Association between smoking/vaping/cannabis use, body habitus (height, BMI), and recurrence risk.
    - Site-level factors (availability of thoracic surgery, ambulatory devices, local guideline presence) as predictors of management choice and adherence.
5. Surgical intervention
    - Indications for surgery (persistent air leak, recurrent pneumothorax, patient preference, high-risk anatomy).
    - Surgical approach: VATS, open thoracotomy, robotic-assisted, or other.
    - Technique details: bullectomy/bleb resection, mechanical or chemical pleurodesis (e.g., talc, doxycycline).
    - Intraoperative complications, duration of surgery, and need for conversion to open procedure.
    - Post-operative outcomes: time to air leak resolution, chest drain duration, hospital stay, recurrence, and functional recovery.

6. System-level variation
    - Explore disparities in time to intervention and access to surgical services by geography and healthcare setting

DEFINITIONS AND AUDIT STANDARDS

DEFINITIONS:

- **Primary spontaneous pneumothorax (PSP):** Occurs without clinically apparent underlying lung disease, most often in otherwise healthy adolescents and young adults.
- **Secondary spontaneous pneumothorax (SSP):** Occurs in the presence of known or suspected underlying lung pathology (e.g., COPD, asthma, cystic fibrosis, interstitial lung disease, Marfan syndrome, Birt-Hogg-Dubé, lymphangioleiomyomatosis, tuberous sclerosis complex, alpha-1 antitrypsin deficiency).
- **Persistent air leak:** Ongoing air leak beyond 48–72 hours after initial intervention, documented clinically or via bubbling in a water-seal system.
- **Pneumothorax size:** Should be measured and documented using the method applied locally (e.g., BTS criteria, American College of Chest Physicians (ACCP) method, Collins method, percentage collapse on CXR/CT). The method used must be recorded.
- **Age groups for analysis:** Patients are stratified as pediatric (<18 years) or adult (≥18 years); exact age is recorded to allow continuous and subgroup analyses.

- **Surgical intervention:** Any operative procedure performed to manage pneumothorax, including VATS, thoracotomy, robotic-assisted, or hybrid approaches.
- **Surgical technique details:** Include type of resection (bleb, bullectomy), pleurodesis method (mechanical, chemical), and conversion to open approach if applicable.

AUDIT STANDARDS:

Derived from recent international guidelines (1-4):

1. **Symptom-based management:** Documentation that clinical symptoms and stability, rather than pneumothorax size alone, guided the initial management decision.
2. **Imaging:** Chest radiograph (CXR) performed before treatment decision. CT performed only when clinically indicated (e.g., atypical presentation, suspicion of underlying pathology, or surgical planning).
3. **Choice of initial intervention:** If intervention required, needle aspiration or small-bore (≤14F) drain used as first-line, unless contraindicated.

4. **Chest drain practice:**
    - Drain size documented (French size).
    - Use of suction recorded; suction applied only when guideline criteria are met.
5. **Catheter/drain removal:** Removal performed in staged manner after evidence of re-expansion (clinical or radiographic) and absence of air leak, with removal and confirmation documented.
6. **Escalation to surgery for persistent air leak** beyond 48–72 hours or recurrence must be documented.
7. **Surgery:** Surgical approach, operative technique, and intraoperative findings should be recorded.

8. **Outcomes:** Postoperative outcomes, including complications, chest drain duration, recurrence, and length of stay, must be captured.
9. **Follow-up plan:** Outpatient follow-up documented at discharge, including recurrence counselling and lifestyle advice (e.g., smoking cessation, return to sport/air travel).

STUDY DESIGN

Multicentre, international, prospective observational cohort study of consecutive patients presenting with spontaneous pneumothorax. Participating centres will enrol all consecutive eligible patients during one or more prespecified 14-day consecutive data collection windows within the overall study recruitment period from 4 May 2026 to 15 November 2026. Each centre may participate in one or more collection windows depending on local capacity. All diagnostic and management decisions will remain entirely at the discretion of the treating clinical teams (observational design); the study will record processes of care, interventions and outcomes. Follow-up assessments occur at 30 days and 12 months after the index presentation to capture recurrence, further interventions, and long-term outcomes.

Key features:

Prospective collection of clinical, process, and outcome data using a standardized CRF.

Single unified cohort capturing exact age for continuous and categorical analyses; primary stratification: pediatric (<18 years) vs adult (≥18 years).

Multilevel data structure with patients clustered within hospitals and countries for adjusted analyses.

STUDY SETTING

- **Eligible sites:** Any hospital or healthcare facility that evaluates and/or manages spontaneous pneumothorax, including emergency departments, general hospitals, tertiary referral centres, and children's hospitals. Both centres with on-site thoracic surgery and centres that transfer patients for surgical care may participate.
- **Geographic scope:** Global, open to sites in all world regions. Participating sites will complete a site survey before data entry to document local resources and care pathways (see Site Survey template). Key site-level items collected include: hospital type, paediatric/adolescent services, on-site thoracic surgery availability, paediatric anaesthesia availability, ambulatory device availability, typical caseload, and whether a local SP guideline/pathway exists.
- **Resource-stratified analysis:** Centres will be classified by World Bank income group or Human Development Index to enable comparisons by resource setting.

Operational requirements for centres:

- Willingness to enroll consecutive patients during agreed windows and to allow local independent validation of case ascertainment.
- Ability to enter data into the central REDCap database.
- Local lead clinician responsible for data completeness and sign-off.

STUDY POPULATION

Patients presenting to participating centres with spontaneous pneumothorax whose initial (index) management begins at the participating site.

INCLUSION CRITERIA

1. Patient aged <18 years (pediatric) or ≥18 years (adult).
2. Presentation to a participating site with spontaneous pneumothorax (primary or secondary), where the index management episode (observation, aspiration, drain insertion, ambulatory device, or surgery) is started at the participating site during the data collection window.

3. Patient is managed at the participating centre for the index episode (this includes those managed entirely as outpatients/ambulatory if the initial management decision and device insertion occur at the site).
4. Signature of the informed consent for participation and consent to the processing of personal data

Notes: First-episode and recurrent SP presentations are eligible; record whether the event is a first ipsilateral episode, first-ever SP, or a recurrence.

Handling Recurrent Episodes

- Each patient should have a single record within the registry.
- Within that record, all subsequent ipsilateral or contralateral recurrences during the study period (and their management episodes) must be documented in the designated recurrence fields of the CRF.
- For each recurrence, record:
    - Date of recurrence.
    - Side (ipsilateral/contralateral).
    - Management strategy used (observation, aspiration, drain insertion, surgery, ambulatory device).
    - Outcome (resolution, persistent air leak, complications).
- If a patient presents multiple times for the same ongoing episode, capture all escalations (e.g., drain insertion after failed aspiration, surgical referral after persistent leak) within the same index episode section of the CRF.
- The CRF will therefore contain:
    - Index episode section (initial presentation and management).
    - Recurrence section (repeatable fields for subsequent episodes within 1 year of follow-up).

EXCLUSION CRITERIA

- **Traumatic pneumothorax** (blunt or penetrating trauma).
- **Iatrogenic pneumothorax** (clearly procedure-related, e.g., central venous catheter insertion, thoracic surgery, pleural biopsy, barotrauma from mechanical ventilation), unless the treating team judges the presentation to represent a

spontaneous pattern and elects to treat it as spontaneous; such cases may be included but must have etiology field documented.

- **Perioperative/intraoperative pneumothorax** that occurs in the context of an intended thoracic procedure and is not managed as a community spontaneous pneumothorax.
- **Duplicate entries** for the same clinical episode.

STUDY PROCEDURES

DATA COLLECTION

1. **Case Report Form (CRF):** Data will be entered into a secure web-based REDCap database using standardized CRFs. Mandatory core variables (age, episode classification, management, outcomes) will be required fields to minimize missingness.
2. **Timing:** Data should be recorded prospectively during the index admission/management episode and supplemented by retrospective review of medical records at discharge, 30 days, and 1 year.
3. **Variables collected:**
    - **Patient-level:** demographics, comorbidities (including genetic syndromes with increased SP risk), lifestyle factors (smoking/vaping/cannabis), presentation details, imaging.
    - **Episode-level/Escalation to surgery**

        i. Indication for surgery (persistent air leak, recurrence, other).
        ii. Surgical approach: VATS, open thoracotomy, robotic-assisted, or hybrid.
        iii. Technique details: bullectomy/bleb resection, mechanical or chemical pleurodesis, other adjuncts.
        iv. Intraoperative complications.
        v. Duration of surgery and anesthesia.
        vi. Postoperative outcomes: chest drain duration, time to air leak resolution, complications, length of stay, readmission.

- **Recurrence events:** subsequent ipsilateral or contralateral pneumothoraces documented under the same patient record (date, side, management, outcome).
- **Site-level:** resources, local pathways, surgical access, paediatric/adult service capacity.

4. **Quality control:** Built-in logic checks, mandatory fields, and central data monitoring will reduce entry errors. Local validators will perform 2-week case ascertainment audits.

FOLLOW-UP PERIOD

- **30-day follow-up:**
  - Data collected via medical record review and/or telephone/email contact (as permitted locally).
  - Outcomes recorded: recurrence, complications, readmission, persistent air leak, further intervention, survival.
- **12-month follow-up:**
  - Outcomes: ipsilateral/contralateral recurrence, further interventions (e.g., VATS, pleurodesis), complications, mortality.
  - Functional outcomes: return to school/work/sport, patient-reported recovery (where available).
  - Quality of life tools may be included optionally at site discretion.
- **Loss to follow-up:**
  - Sites must document the method of follow-up (hospital records, clinic visits, phone, email) and the reason if a patient is lost to follow-up.
  - Core outcomes (recurrence and further procedures) should be obtainable from hospital records in most settings.

STATISTICAL CONSIDERATION

PRIMARY OUTOME MEASURE

The primary outcome is the proportion of patients whose index episode management adhered to international guideline-derived audit standards**,** assessed separately in pediatric (<18 years)

and adult (≥18 years) cohorts. Adherence will be defined as meeting all applicable binary audit standards for:

- symptom-based decision-making,
- appropriate imaging,
- initial intervention strategy,
- drain use and suction practice,
- escalation for persistent air leak,
- staged drain removal, and
- documented follow-up plan.

SECONDARY OUTCOME MEASURES

1. **Process-of-care measures**
    - Variation in first-line management (observation, aspiration, small-bore drainage, large-bore drainage, ambulatory device, immediate surgery).
    - Imaging utilisation (CXR vs CT vs ultrasound).
    - Chest drain characteristics (size, suction use, removal practices).
    - Access to and timing of surgical referral.
2. **Short-term outcomes (index admission to 30 days)**
    - Time to lung re-expansion.
    - Incidence and duration of persistent air leak (>48–72h).
    - Complications: infection, bleeding, tube dislodgement, re-expansion pulmonary edema.
    - Length of stay (LOS).
    - 30-day readmission rates.
    - 30-day mortality (expected to be very low but captured for completeness).
3. **Long-term outcomes (1 year)**
    - Recurrence rates (ipsilateral and contralateral).
    - Need for definitive surgical intervention (VATS, pleurodesis, thoracotomy).
    - Functional recovery: return to school, work, or sport.
    - Patient-reported recovery or quality of life (if collected at site).

- Surgical outcomes: recurrence rate following surgical intervention, postoperative complications, readmission, need for re-intervention.
- Comparative outcomes by surgical approach (VATS vs open vs robotic).
- Time to return to baseline activity or functional recovery post-surgery.

4. **Predictors of outcome**
   - Patient-level: age, sex, BMI, smoking/vaping/cannabis use, comorbidities, genetic syndromes.
   - Episode-level: PSP vs SSP, initial management choice, escalation of care.
   - Site-level: presence of local guidelines, surgical availability, resource setting.

CONTROL OF BIAS AND CONFOUNDING

- **Consecutive enrolment:** All eligible patients during data windows will be included to reduce selection bias.
- **Screening logs and validation:** Independent local validation will ensure complete case ascertainment and reduce underreporting bias.
- **Standardised CRF:** Reduces misclassification bias; mandatory fields ensure core data completeness.
- **Multilevel modelling:** Accounts for clustering at hospital and country level to reduce confounding from site-specific practices.
- **Adjustment for confounders:** Regression models will adjust for key covariates including age, sex, PSP vs SSP, smoking status, comorbidities, and resource availability.
- **Surgical approach** and center-level surgical expertise will be considered as site-level factors in multilevel modeling to adjust for potential confounding in outcomes.
- **Sensitivity analyses:** Excluding patients with incomplete data; stratifying by PSP vs SSP; excluding sites with poor validation.

DATA ANALYSIS AND SAMPLE SIZE

Analysis approach:

- Descriptive statistics for patient characteristics, management, and outcomes, stratified by pediatric vs adult cohorts.

- Descriptive and comparative analyses of surgical approaches (VATS vs open vs robotic) regarding short- and long-term outcomes
- Categorical variables: proportions with 95% confidence intervals; comparisons by χ^2 or Fisher's exact test.
- Continuous variables: medians with IQR or means with SD; comparisons by t-test or Mann–Whitney U.
- Multilevel logistic regression: predictors of adherence and short-term outcomes, with hospital and country as random effects.
- Multivariable regression to evaluate predictors of surgical referral, approach selection, and postoperative outcomes, adjusting for patient, episode, and site-level factors.
- Cox proportional hazards modelling: time to recurrence, adjusted for patient and site factors.
- Interaction terms: test whether age group (<18 vs ≥18) modifies associations between management strategies and outcomes.

Sample size considerations:

We aim to recruit a pragmatic target of ~2,000 patients from participating centres worldwide, including a minimum of 300 pediatric (<18 years) participants.

This target is based on feasibility estimates from comparable international, investigator-led observational studies (e.g., GlobalSurg, GECKO, EuroAIM), which achieved sample sizes of 1,500–3,000 patients over similar 6–12 month recruitment windows across 100–200 hospitals. Given the relatively low incidence of spontaneous pneumothorax compared with acute appendicitis or cholecystectomy, this target is considered realistic for a global collaboration involving both adult and pediatric centres.

At this scale, the precision of the primary endpoint (global adherence to guideline-derived audit standards) will allow estimation of a proportion (e.g., 60%) with a 95% confidence interval of approximately ±2–3 percentage points, providing adequate statistical power for subgroup comparisons by age group, management strategy, and resource setting. A formal feasibility and accrual review at 12 months will be conducted to re-estimate the achievable final sample size and extend recruitment if necessary to ensure robust subgroup analyses, particularly for pediatric and surgical cohorts.

DATA GOVERNANCE

The study will be coordinated by the GASPOUT Steering Committee, supported by National Leads in each participating country. National Leads will liaise with Local (Hospital) Leads and mini-teams of collaborators to ensure standardised implementation of study procedures, ethical compliance, and data validation.

This is a non-profit, investigator-led study with no external sponsors or funding. Participating centres will not receive financial support for their involvement.

Data ownership

- All data remain the property of the participating centres.
- The coordinating group (GASPOUT Steering Committee) will act as data guarantor for the merged international dataset.
- Centres may access and use their own local data for audit, quality improvement, or local presentations/publications without further approval.
- Analyses of the combined international dataset require approval by the Steering Committee and adherence to authorship/collaborative rules.

Data storage and security

- Data will be collected using a secure, password-protected, web-based electronic data capture system (e.g., REDCap).
- All data entered into the central database will be de-identified:
    - No patient names, addresses, or full dates of birth will be uploaded.
    - Each centre will maintain a secure local "linkage file" mapping study ID to hospital identifiers, stored according to local regulations.
- Servers will comply with applicable data protection standards (HIPAA, GDPR, and local equivalents).
- Data transmission will be encrypted (SSL/TLS).

Data quality assurance

- Mandatory fields and range checks built into the CRF will reduce missing or implausible entries.
- Automated data validation reports will be generated monthly and returned to sites for query resolution.
- Independent local validators at each site will audit case ascertainment and accuracy for a 2-week sample period.

Data retention and archiving

- Each centre will retain their local linkage file securely for at least 5 years or as required by local regulation.
- The central de-identified dataset will be archived securely at the lead institution for a minimum of 10 years.
- Requests for data access beyond the core study team will require Steering Committee approval and may be subject to data-sharing agreements.

Data sharing and authorship

- Collaborative authorship will follow a contributorship model: all participating sites with validated data will be recognised in group authorship.
- Secondary analyses using the international dataset will be encouraged; proposals must be submitted to the Steering Committee for review.
- Approved analyses will be conducted either centrally or under a data-sharing agreement, with clear rules for authorship, acknowledgements, and responsibilities.

LOCAL PROJECT REGISTRATION

Regulatory classification: This study is designed as a prospective, multicentre, observational audit of usual clinical practice. No interventions are mandated by the protocol; all management decisions remain at the discretion of the treating clinicians.

Local approvals:

- Each participating centre is responsible for obtaining all required local approvals before commencing data collection. This may include:
    - Institutional Review Board (IRB) or Research Ethics Committee (REC) approval.
    - Audit or service evaluation registration (where observational audits do not require formal ethics approval).
    - Research and Development (R&D) or institutional governance registration.
- The classification of the study (audit, service evaluation, or research) will depend on local regulations. The coordinating team will provide template protocol documents, patient information sheets, and consent/assent forms (where required) to support submissions.

Consent requirements:

- In some jurisdictions, prospective informed consent may not be required for observational audits of standard care.
- Where required, sites must obtain appropriate consent/assent from participants or guardians (<18 years) before data entry.
- Centres must record the consent pathway applied (waiver / parental consent / assent + consent).

Registration log: Each site must maintain a record of:

- Local approval reference number.
- Date of approval.
- Type of approval (audit/service evaluation/research ethics).
- Name and contact details of the local Principal Investigator (PI).

Activation: Sites may begin data collection only after confirmation of local registration/approval and completion of the site survey.

Data sharing agreement: A formal Data Sharing Agreement (DSA) is not mandatory for participation in this observational study. However, upon request from participating institutions, a standard, non-negotiable DSA template can be provided by the coordinating centre to facilitate local institutional requirements. This DSA will define the scope of data transfer (pseudonymized data), governance, and data protection standards, consistent with GDPR and international best practice

AUTHORSHIP

Principles

- Authorship will follow the recommendations of the International Committee of Medical Journal Editors (ICMJE)**.**
- The GASPOUT study will adopt a collaborative authorship model, recognising both individual contributions and group collaboration.
- Transparency and inclusivity are key: all centres that contribute validated data will be acknowledged in publications.

Types of authorship

1. **Writing group authorship**
    - A core Writing Group, appointed by the Steering Committee, will draft the primary manuscripts.
    - Members will be selected to ensure representation across specialties (respiratory, emergency medicine, surgery, pediatrics), geographical regions, and age groups (<18 vs ≥18).
    - Authorship order will reflect contribution to study conception, design, data analysis, and manuscript drafting.
2. **National Leads**

    - Each participating country or region will appoint one or more National Leads, depending on case volume and geographical distribution.
    - National Leads will coordinate study registration, ethics or audit approvals, and site engagement within their country.
    - They will support hospital teams with protocol compliance, data completeness, and translation of materials where required.
    - National Leads will act as the primary point of contact between participating hospitals and the GASPOUT Steering Committee.
    - To qualify for recognition as National Lead Author, individuals should oversee at least three active sites or a minimum of 50 validated cases within their country, ensure local data validation and high data completeness, and contribute to study dissemination and national reporting.
    - National Leads will be recognised as PubMed-indexed authors in the main GASPOUT Collaborative publication and listed in the primary author appendix under the heading *National Leads*.

3. **Collaborator authorship (group authorship)**
    - All investigators at participating centres who contribute to case identification, data collection, or validation will be listed as PubMed-indexed collaborators under the group name: “GASPOUT Collaborative.”
    - Each participating hospital will form a mini-team comprising up to five collaborators responsible for patient inclusion, data entry, and validation.

Team structure:

- Up to two Consultant or Senior Leads per hospital, ideally representing both adult and pediatric care streams (for example, one general or thoracic surgeon and one pediatric surgeon).
- Up to five additional collaborators, such as junior doctors, residents, or medical students, actively involved in patient identification, data collection, and follow-up.
- One independent validator, appointed separately, who will verify data completeness and accuracy for at least a 2-week period. The validator's contribution will be recognised in addition to the five-member mini-team.

Organisation of data collection:

- Teams will collect data on consecutive eligible patients within one or more of the pre-specified 14-day data collection windows during the recruitment period.
- Hospitals may register separate consultant leads and independent teams for adult and pediatric cohorts if these services are delivered by distinct clinical groups. If adults and paediatric surgery is delivered by separate surgical teams, then sites can register separate consultant leads for both specialties. In that case, there will be mini-teams for each specialty per distinct data collection period. With the exception of the aforementioned distinction between the pediatric team and the adult team, if multiple sub-teams are established, each must cover a distinct two-week period, with no overlap between them.

Authorship recognition:

- All collaborators meeting data quality and completeness thresholds (≥90% case ascertainment and ≤10% missingness for mandatory variables) will be recognised as PubMed-indexed authors under the GASPOUT Collaborative group name.
- Each hospital's Consultant Leads will be named in the group authorship line and acknowledged individually in the main publication appendix.

- The independent validator will be acknowledged separately in the collaborator listing for transparency.

4. **Steering Committee and Advisory Board**
    - Members of the Steering Committee and Advisory Board will be acknowledged as authors or collaborators in line with their contribution.
5. **Secondary analyses**
    - Secondary or sub-analyses will be encouraged. Authorship of these outputs will follow the same rules: writing group authors plus contributing collaborators from participating centres with validated data relevant to the analysis.

Authorship eligibility

To qualify for collaborator authorship on the primary manuscript, each centre must:

- Achieve ≥90% case ascertainment (validated by independent audit).
- Achieve ≤10% missingness for mandatory core variables.
- Submit data for at least one complete 2-week window (or equivalent continuous period).
- Complete the site survey and validation exercise.

Centres that do not meet these thresholds may still be acknowledged in supplementary material but not listed as PubMed-indexed collaborators.

APPENDIX A: CASE REPORT FORM (CRF)

See CRF file

APPENDIX B: SITE SURVEY

See Site Survey file

APPENDIX C: METHODS FOR PNEUMOTHORAX SIZE ESTIMATION

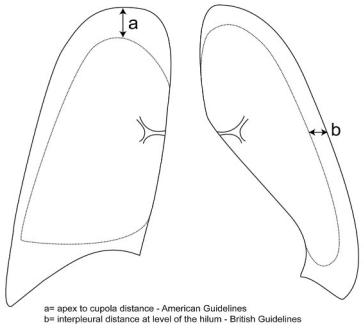
Rationale:

Pneumothorax size is often used to guide management, though modern guidelines emphasize

symptoms over size alone. Different methods exist in the literature and guidelines; centres must specify which method is applied for each patient.

1. **British Thoracic Society (BTS) method** (1, 7)

- **Definition:** Distance between lung margin and chest wall at the level of the hilum on chest radiograph.
- **Cut-offs** (1, 7)**:**
    - *Small*: <2 cm at the hilum
    - *Large*: ≥2 cm at the hilum



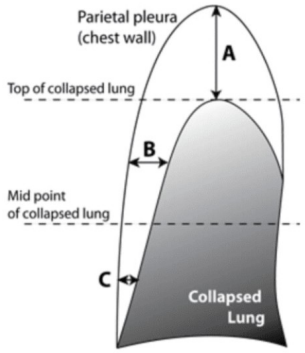
2. **American College of Chest Physicians (ACCP) method** (8)

- **Definition:** Apex–cupola distance = distance from lung apex to cupola (chest wall apex) on chest radiograph.
- **Classification** (8)**:**
    - *Small*: <3 cm apex–cupola distance
    - *Large*: ≥3 cm apex–cupola distance

3. **Collins method** (9)

- **Definition:** Calculates percentage pneumothorax volume based on interpleural distances measured on chest radiograph.
- **Formula:**

  % Pneumothorax = 4.2 + (4.7 × A) + (4.2 × B) + (6.9 × C)
    - A = apical interpleural distance (cm)
    - B = interpleural distance at midpoint of upper half of lung (cm)
    - C = interpleural distance at midpoint of lower half of lung (cm)



4. **Other methods (must specify in CRF)**

Examples:

- **Light index:** Ratio method using apex–cupola distance.
- **CT volumetry:** 3D reconstruction providing exact pneumothorax volume.
- **Bedside ultrasound:** Qualitative assessment (lung sliding absent, lung point present).

APPENDIX D: STUDY DEFINITIONS

AMERICAN SOCIETY OF ANAESTHEGIOLOGISTS (ASA) CLASSIFICATION

ASA Physical Status Classification (10)	Definition	Examples
ASA 1	A healthy patient	A fit, nonobese, nonsmoking patient with no underlying disease and good exercise tolerance
ASA 2	A patient with systemic disease that is mild	A patient with no functional limitations and a well-controlled disease, obesity with a BMI 30-40, frequent social drinking, or current cigarette smoking
ASA 3	A patient with systemic disease that is severe but not life-threatening	A patient with some functional limitation due to poorly controlled moderate/severe disease(s), morbid obesity with BMI 40 or above, substance abuse, end-stage renal disease undergoing regular dialysis, implanted pacemaker, or remote history of coronary or intracerebral ischemic event (not within the past 3 months)

ASA 4	A patient with "severe systemic disease that is a constant threat to life"	A patient with substantial functional limitations due to severe, life-threatening diseases, such as coronary or intracerebral ischemic event within the past 3 months, severe end-organ dysfunction (cardiac, pulmonary, renal), ongoing coagulopathy, and shock states
ASA 5	A comatose patient who is "not expected to survive without the operation"	Ruptured aneurysm, multisystem trauma, or extensive intracranial hemorrhage with mass effect
ASA 6	A brain-dead patient whose organs are being procured for transplantation into another patient	

CLINICAL FRAILTY SCALE

Clinical Frailty Scale Components (11)

1. Very Fit: People who are robust, active, energetic, and motivated. These people commonly exercise regularly. They are among the fittest for their age.
2. Well: People who have no severe disease symptoms but are less fit than category 1. They exercise or are very active occasionally, e.g., seasonally.
3. Managing Well: People whose medical problems are well-controlled but are not regularly active beyond routine walking.
4. Living With Very Mild Frailty: Previously named "Vulnerable," While not dependent on others for daily help, symptoms often limit activities. A common complaint is being "slowed-up" and being tired during the day.
5. Living with Mild Frailty: These people usually have more evident slowing and need help in higher-order instrumental activities of daily living (IADLs) such as finance, transportation, heavy housework, and medication management. Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation, and housekeeping.
6. Living With Moderate Frailty: People need help with all outside activities and housekeeping. Inside often have problems with stairs, need help with bathing, and may need minimal assistance with dressing.

7. Living With Severe Frailty: Completely dependent for cognitive and physical personal care. However, they seem stable and not at high risk of dying (within six months).
8. Living with Very Severe Frailty: Completely dependent for personal care and approaching end of life. Typically they could not recover even from minor illnesses.
9. Terminally Ill: Approaching the end of life. This category applies to people with a life expectancy of under six months who are not otherwise living with severe frailty. (Many terminally ill people can still exercise until very close to death.)

INDICATION FOR SURGERY

1. **Persistent air leak**

- Ongoing air leak >48–72 hours after initial management (drain or aspiration) without evidence of resolution.
- Record duration of leak in hours/days.

2. **Recurrence**

- Ipsilateral recurrence (document date and management of prior episode).
- Contralateral recurrence (new spontaneous pneumothorax on opposite side).

3. **Radiological findings**

- Large or multiple blebs/bullae on imaging (CXR, CT, or intraoperative) deemed high risk for recurrence.
- Record size, number, and location if available.

4. **Occupational or activity-related risk**

- Patients whose occupation or lifestyle carries unacceptable recurrence risk (e.g., pilots, divers, professional athletes).

5. **Patient preference**

- Informed choice of patient/guardian for definitive surgical management despite absence of other standard indications.

6. **Other clinical reasons**

- Examples: synchronous procedures (e.g., biopsy for suspected cystic lung disease), poor tolerance of recurrence, or comorbidities necessitating definitive control

CLAVIEN-DINDO CLASSIFICATION SYSTEM

Grade (12)	Definition
I	Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics.
II	Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
IIIa	Requiring surgical, endoscopic or radiological intervention, not under general Anaesthetic (GA).
IIIb	Requiring surgical, endoscopic or radiological intervention, under GA.
IVa	Life-threatening complications requiring critical care management with single organ dysfunction, or neurological complications including brain haemorrhage and ischemic stroke (excluding TIA).
IVb	Life-threatening complications requiring critical care management with multi-organ dysfunction.
V	Death

DEFINITION OF COMPLICATIONS

- **Infective complications**
    - Empyema: pleural infection requiring antibiotics ± drainage.
    - Surgical site infection: per CDC criteria (superficial, deep, organ/space).
    - Pneumonia: new infiltrate + compatible symptoms/signs ± positive cultures.

- **Bleeding complications**
    - Haemothorax: blood in pleural space requiring drainage, transfusion, or reoperation.
    - Significant perioperative bleeding: >500 mL blood loss, transfusion, or haemodynamic instability.
- **Pulmonary complications**
    - Re-expansion pulmonary oedema: new pulmonary infiltrates with hypoxia after rapid re-expansion.
    - Prolonged/persistent air leak: bubbling or documented leak >48–72 hours post-intervention.
    - Respiratory failure: requiring intubation or escalation of ventilatory support.
- **Device-related complications**
    - Drain displacement: accidental removal, malposition, or blockage requiring replacement.
    - Drain site infection: erythema, pus, or positive culture at insertion site.
    - Ambulatory device failure: malfunction requiring removal or replacement.
- **Anaesthetic complications**
    - Airway complications (e.g., difficult intubation, bronchial blocker misplacement, reintubation).
    - Sedation-related adverse events (e.g., hypoxia, hypotension requiring intervention).
- **Other surgical complications**
    - Conversion to open thoracotomy (not intended at outset).
    - Postoperative chylothorax: confirmed by pleural triglyceride >110 mg/dL or chylomicrons.
    - Postoperative prolonged air leak (>5 days post-surgery).

Mortality

- All-cause mortality will be recorded at 30 days and 1 year, with attribution to pneumothorax or treatment where possible.

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