Improving Research Quality: Proposed Minimum Dataset, Patient Reported Outcomes, and Methodology Criteria for Interventional Trials of Primary and Incisional Hernia Repair.

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Introduction

Ventral hernia (VH) prevalence is increasing due to increasing age, obesity, and improvements in ITU care (1). These hernias can be large and extremely difficult to repair (2). High recurrence rates after surgical repair (3) have attracted increased research interest over the last twenty years and a new subspecialty of Abdominal Wall Reconstruction (AWR) has emerged. These abdominal wall surgeons are performing interventional trials aiming to advance repair techniques and improve patient outcomes (4,5). To date, randomised trials suggest that mesh has lower recurrence rates than suture repair (6), small bites closure of a midline laparotomy reduces incidence of subsequent incisional hernia (7), and quality of life is improved and recurrence reduced with primary fascial closure versus bridged repairs (8,9).

However, recent systematic reviews (10,11) suggest that VH interventional trials collect data that is poorly defined, is inconsistent between researcher groups, and reports post-operative outcomes that are measured and detected in many different ways. One review found sixty-four different post-operative outcomes reported, a length of follow-up ranging from 1 to 64 months, and identified five different methods for detecting recurrence (10). Such inconsistency encourages highly heterogenous data, which frustrates comparisons via both narrative review and meta-analysis.

To rectify this, we aimed to construct a minimum dataset for VH interventional trials. Our early discussions identified that primary and incisional hernias are increasingly being investigated and treated as separate pathologies, since their aetiology differs (12). Indeed, published guidelines recommend that, *"when studying ventral hernias, the analysis of primary ventral hernias should be done separately from the analysis of incisional and recurrent ventral hernias"* (13). Our panellists decided, therefore, to develop two minimum datasets, for primary and incisional VHs respectively. These two datasets will facilitate data pooling, allowing researchers to better explore the impact of patient demographics, hernia characteristics, and intra-operative variables on both operative and patient outcomes. We used an expert panel to identify and define variables, and to standardise their measurement and detection.

Methodology and Design

We based our methodology on the Nominal Group Technique (NGT). NGT is a procedure that facilitates effective group decision making by giving each individual an equal chance to provide input into a defined problem (14). NGT provides large amounts of data over a short period of time (15), reduces 'social loafing' (16), and can be used to establish priority lists (17).

Before the exercise began, panellists were asked to assume that the minimum datasets will be for interventional VH trials being conducted in a modern hospital with routine follow up and outpatient diagnostic tests. Panellists were asked to assume that these datasets will provide a template for interventional trials of elective VH repair where this is the primary indexed procedure. This is particularly important for retrospective studies where the primary

procedure is sometimes unclear; i.e. the minimum dataset does not apply to operations where the primary indexed procedure is not VH repair or is unclear. Parastomal hernias were excluded, but it was anticipated the dataset could be adaptable for these. SGP, SH and SM acted as the steering committee throughout and did not vote. As per NGT stipulations, during group discussions they remained impartial and encouraged panellists to debate while not contributing themselves. Development consisted of four phases; expert panel selection (phrase 1), development of a maximum dataset (phase 2), a focused group meeting and maximum dataset completion (phrase 3), followed by rounds of voting and ranking (phase 4). The four phases of NGT; silent generation of ideas, ideas sharing, group discussion, and voting and ranking, were used to create the minimum trial datasets (14). The four phases of dataset development are displayed in the flowchart, Figure 1.

Figure 1: Flowchart showing the stages of minimum dataset development. The Nominal Group Technique to guide our methodology.
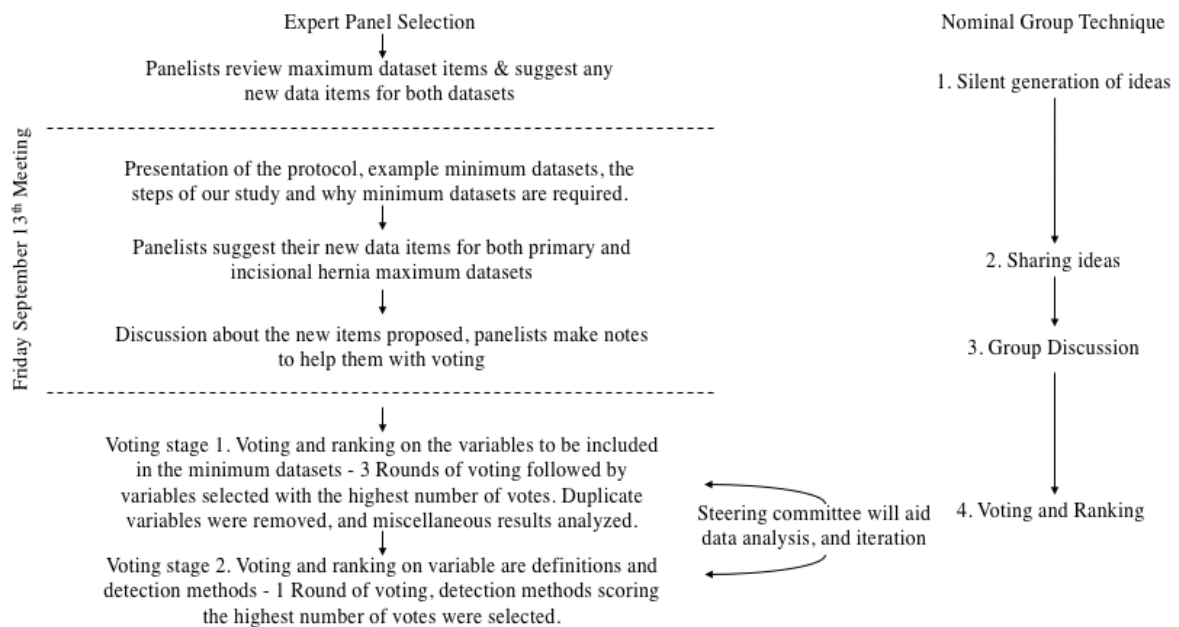
Phase 1: Expert Panel Selection

SGP and ACJW selected a group of European panellists with well-established specialist academic and clinical interest in VH repair. Several panellists are leading members of the European, British, and Danish Hernia Societies. In total, 15 expert panellists were asked to take part. All panellists gave written consent to their participation and committed to complete the study, to add variables to the maximum dataset, to attend a focused group meeting in Hamburg at the European Hernia Society's 2019 conference, to participate in rounds of voting, and to adhere to NGT format during group discussions. Panellists were also asked to adhere to COPE criteria (18), thereby authenticating their co-authorship. Lastly, panellists were asked to declare any conflicts of interest (COIs) on their consent form. Those with COIs were asked to withdraw if they believed these would affect their judgement.

Because patient and public involvement is deemed essential when formulating patient reported outcomes measures (PROMs), we included two patient advocates. Consequently, 17 panellists contributed to suggesting, disputing, prioritising and ranking PROMs. The 15 expert hernia surgeons also contributed to the analysis and the prioritising of the clinical variables.

2: Development of a Maximum Dataset

To develop a maximum dataset, two prior systematic reviews (10,11) were interrogated to identify and extract variables collected during VH interventional trials. These variables were listed in Microsoft Excel (Microsoft Excel for Mac 2011 v. 14.5.9, Microsoft Corporation, Washington), (Online Resource 1). This list contains an extensive catalogue of variables that could be potentially incorporated into the minimum datasets. The same list was used to develop both primary and incisional hernia minimum datasets. SGP and SM grouped these variables into four categories; 1) pre-operative variables (patient and hernia variables), 2)

intra-operative variables, 3) post-operative variables, 4) patient reported outcomes measures. A fifth section of methodological criteria was also compiled from interventional trial tools used for previous methodological analysis (19–24). The provisional maximum dataset was emailed to panellists for analysis and review. Panellists were asked to add any additional variables that they felt warranted inclusion (satisfying NGT, Silent generation of ideas, (14)).

3: Focused Group Meeting and Maximum Dataset Completion

All panellists were then asked to attend a focused group meeting to debate and discuss the contents of the maximum datasets. Initially, SGP gave a presentation explaining the protocol and meeting purpose. Reasons for establishing a standardised minimum dataset for interventional trials was presented and example datasets from other disciplines given to all panellists. Thereafter, panellists fulfilled two tasks:

1) Via 'round robin' structured discussions, individual panellists were given the opportunity to detail any additional variables they had added and theie rationale for this (satisfying NGT, sharing ideas, (14)).

2) The additional variables were then discussed and their inclusion debated (satisfying NGT, group discussion, (14)). If further new variables arose from these discussions, these were also added to the maximum dataset if deemed appropriate. During discussions panellists could make notes. The two patient advocates contributed to discussions concerning PROMs.

4. Voting and Ranking

Panellists were sent the finalised maximum dataset following the meeting. Voting occurred in three stages (NGT: Voting and Ranking, (14)). Initially panellists were sent a table asking the number of individual variables they considered suitable for each category of both datasets (Online Resource 2). Thereafter, they selecting from the maximum dataset those variables they considered should be included in the minimum datasets. Finally, panellists voted on variable definitions and detection methods. Voting used electronic mail. During voting the steering committee facilitated results tabulation, data interpretation and analysis, and iteration. Voting for both primary and incisional hernia datasets occurred concurrently.

Stage 1: Number of dataset variables

After analysing the maximum dataset, each panellist was asked to suggest a number of variables for each variable category of both the primary and incisional hernia minimum datasets. SP collected these votes, the results analysed by the steering committee, and a final number of variables was proposed to panellists for approval.

Stage 2: Variables in the Datasets

As described above, a proposed number of variables, X, had been defined for each dataset category. From the maximum dataset, for each category, panellists were then asked to rank their chosen variables/items, from X (most preferred) to 1 (least preferred). Variables scoring greater than 50% of the maximum possible score for a category (maximum = 15 x X; 17 x X, for PROMs) were defined as achieving consensus, and were included in the final minimum dataset. Variables attracting no votes were deleted from the next round of voting. If Y

variables reached consensus for a category in Round 1, then panellists voted on X-Y variables in that category for Round 2, from X-Y (most preferred) to 1 (least preferred). Again, 50% of the maximum possible score was deemed as reaching consensus. Results from each voting round were disclosed to panellists, and voting continued for three rounds. Thereafter, results of the three voting rounds were analysed by the steering committee. For incomplete categories, remaining variables were selected in order of popularity and duplicate variables removed. Miscellaneous results were discussed amongst the steering committee and removed if appropriate. Thereafter, the finalised minimum datasets were compiled and sent to all panellists for approval.

Stage 3: Variable Definitions and Detection Methods

Panellists then voted on variable definitions and detection methods. For most variables definitions used commonly by hernia surgeons were selected and proposed by the steering committee. Free text space was available for panellists to propose alternative definitions. Where multiple choices were possible for a detection method (e.g. imaging) panellists voted for their preference. Panellists also select their preferred follow-up duration, selecting more than one duration where they deemed appropriate. To improve efficiency, if a variable existed in both minimum datasets, panellists were asked to vote only on how they would detect it for PVH. After voting, panellists were asked if they were happy for their responses to also apply to variables in the IVH dataset and if not, why? Comments and feedback were encouraged. Detection methods and follow-up times achieving the highest number of votes were selected.

At the end of the process, the finalised minimum datasets with their respective variable definitions and detection methods were sent to all panellists for approval.

Results

1. Panellist Selection

All expert hernia surgeons approached agreed to take part in the study. Three panellists MM, MS, and AM joined the study late after voting on the number of variables in the datasets. They therefore did not take part in development of our maximum dataset or in our focused group meeting. Both expert patients approached, SB and ND, agreed to take part.

2. Development and completion of the Maximum Dataset

Our maximum dataset initially contained 245 variables; 22 (9%) patient variables, 19 (8%) hernia characteristics, 20 (8%) intra-operative variables, 32 (13%) post-operative outcomes, 116 (47%) patient reported outcomes, and 36 (15%) methodology criteria, all derived from previous systematic review (10,11). 109 new variables were suggested by panellists;19 (17%) patient variables, 15 (14%) hernia characteristics, 32 (29%) intra-operative variables, 9 (8%) post-operative outcomes, 30 (27%) patient reported outcomes, and 4 (4%) methodology criteria, expanding our maximum dataset to 354 variables. The focused group meeting occured during the European Hernia Society's 41st conference in Hamburg, on Friday September 13th 2019. After structured 'round robin' and group discussions 30 variables were eliminated leaving 324 variables in the maximum dataset; 40 (12%) patient variables, 29 (9%) hernia characteristics, 35 (11%) intra-operative variables, 39 (12%) post-operative

outcomes, 141 (44%) patient reported outcomes, and 40 (12%) methodology criteria (Online Resource 3).

3. Voting and Ranking

Stage 1: Number of dataset variables

For the PVH minimum dataset panellists voted for a mean of 60 variables (range 29 to 97). For each category votes averaged 15 (25%) patient variables, 10 (17%) hernia characteristics, 19 (32%) intra-operative variables, and 16 (26%) post-operative outcomes. For the IVH minimum dataset panellists voted for a mean of 71 variables (range 36 to 104); 16 (22%) patient variables, 17 (24%) hernia characteristics, 21 (29%) intra-operative variables, and 17 (24%) post-operative outcomes. Panellists, including the patient representatives, voted for 25 patient reported outcomes. Finally, panellists voted for an average of 37 methodology criteria. At this early stage the steering committee felt an intervention was required. The voting had not selected a minimum number of variables for dataset inclusion. After reviewing the literature and analysing current registry (25,26) and trial datasets (27), and the number of variables collected by previous hernia trials (6,28–31) the steering committee proposed 31 variables for the PVH dataset (8 (26%) patient variables, 6 (19%) hernia characteristics, 10 (32%) intra-operative variables, 7 (23%) post-operative outcomes), and 39 variables for the IVH dataset (8 (20%) patient variables, 10 (26%) hernia characteristics, 14 (36%) intra-operative variables, 7 (18%) post-operative outcomes), with 25 PROMs, and 38 methodology criteria. The steering committee informed the panellists of their proposal to reduce the number of variables to reasonable levels, and the rationale for this. All panellists then agreeed with the final number of variables (Online Resource 4).

Stage 2: Variables in the Datasets

Voting commenced on 1st October 2019 and was completed on 10th July 2020 (example voting sheet for Round 1, Online Resource 5). For the PVH dataset 9 variables reached consensus in Round 1; 4 (44%) patient variables, 3 (33%) intra-operative variables, and 2 (23%) post-operative outcomes. After Round 2, 8 more variables reached consensus; 2 (25%) patient variables, 2 (25%) hernia characteristics, 3 (37.5%) intra-operative variables, and 1 (12.5%) post-operative outcomes. A further 7 variables reached consensus after Round 3; 1 patient variable, 2 hernia characteristics, 2 intra-operative variables, and 2 post-operative outcomes. Consequently, 24 of the 31 (77%) variables were selected after 3 rounds of voting (Online Resource 6). For 6 of the 7 remaining, the variables scoring highest and selected most frequently by panellists were added to the dataset. The steering committee made two interventions: 'COPD' which had received a surprisingly low score after Round 3, was added as the last patient variable. 'COPD' had achieved high scores in Rounds 1 and 2, and was therefore selected over 'Frailty', 'Anti-coagulation', and 'No. of co-morbidities'. The committee also decided to add, 'Re-operation rate in 30 days' as an additional outcome, making a total of 8 post-operative outcomes and 32 variables in the final PVH dataset, Table 1 (Online Resource 6).

For the IVH dataset 12 variables reached consensus in Round 1; 5 (42%) patient variables, 1 (8%) hernia characteristic, 4 (33%) intra-operative variables, 2 (17%) post-operative outcomes. After Round 2, 9 more variables reached consensus; 2 (22%) patient variables, 1 (11%) hernia characteristic, 4 (45%) intra-operative variables, and 2 (22%) post-operative outcomes. A further 9 variables reached consensus after Round 3; 4 (45%) hernia

characteristics, 3 (33%) intra-operative variables, and 2 (22%) post-operative outcomes. Consequently, 30 of the 39 variables were selected after 3 rounds of voting (Online Resource 7). For 8 of the 9 remaining, variables scoring highest and selected most frequently by the panellists were added to the dataset. Again, the steering committee intervened twice. 'Pre-operative pneumoperitoneum' was removed as a possible option as it was deemed too rare. 'Mesh overlap' was therefore added to the dataset as an intra-operative variable. To standardise post-operative outcomes, the committee also added 'chronic pain', the next most popular outcome selected. This resulted in a total of 8 post-operative outcomes for both datasets and 40 variables in the final IVH dataset, Table 2 (Online Resource 7).

For the PROMs 11 of the 25 outcomes reached consensus after the 3 rounds of voting; 4 (36%) during Round 1, 5 (46%) during Round 2, and a further 2 (18%) after Round 3 (Online Resource 8). The 4 remaining PROMs from EURAHS QoL (25) and the 6 remaining PROMs from SF-12 (32) scored sufficiently for selection. The last 4 PROMs to achieve a higher enough score, without duplication of previously included PROMs, were proposed by the patient representatives on our panel. Two of these assessed mental health, sexual activity, and 2 focused on decisional regret. For one PROM the steering committee made a small adjustment. For the question; 'Moderate activities, such as moving a table, vacuum cleaning, bowling, or playing golf', 'vacuum cleaning was changed to 'getting dressed' and 'cooking' (Online Resource 8). The final list of 25 PROMs can be seen in Table 3.

For the methodology criteria, panellists could not reach consensus regarding which criteria should be removed from the original list of 40 recommendations. Consequently, during Round 3 we asked all panellists; 'please state whether you agree or disagree with the following: I think all 40 of the original methodology criteria can be used in a checklist for

ventral hernia interventional trials'. All 15 hernia specialists agreed with this statement. These recommended methodological criteria are displayed in Table 4.

Stage 3: Variable Definitions and Detection Methods

This stage involved a single round of voting (Online Resource 10). Prior to voting, accepted variables definitions were selected by the steering committee and sent to panellists for review. After panellists' feedback, two definitions were altered by the steering committee. Three panellists objected to the proposed definition for smoking status (), with one panellist stating; '*Two months abstinence should be required for an ex-smoker, that is clinically relevant in terms of reduction of complications from surgery*'. Consequently, the existing EURAHS definition of smoking status was adopted (25). Secondly, an existing definition for mesh infection could not be identified prior to voting. Therefore, panellists were asked to suggest a definition. Five panellists proposed a new definition, after review and a new definition devised; '*A chronic wound infection, wound sinus, or wound abscess in the location of a prosthetic mesh implant*'. Regarding loss of domain, the Sabbagh volumetric definition was chosen, after receiving 10 votes (67%), compared to 5 for the Tanaka definition. The finalised definitions can be found in column 2 of the completed datasets, Table 1 and Table 2.

Votes for variable detection methods are shown in Online Resource 10. Where panellists were indecisive, they often chose more than one option or occasionally proposed an alternative. For 4 out of 6 pre-operative hernia variables (67%); number of ventral hernia defects, hernia width, diastasis, and loss of domain, panellists selected CT as their preferred option. To grade PVH using the EHS classification system, 'clinical examination' was the

most popular detection method and for reducibility 'clinical examination +/- CT' was most popular. Overall, 12 panellists (80%) chose CT scanning as the method to assess and characterise PVH pre-operatively. For hernia defect area, the only IVH variable panellists were required to vote on, 14 panellists (93%) selected CT.

Panellists also voted for post-operative outcome detection methods (Online resource 10). For wound infection 8 (53%) panellists voted for clinical diagnosis via history and examination. This was adapted by the steering committee to meet the CDC criteria; see Table 1 & 2. For surgical site occurrence, 12 (75%) panellists voted for history and examination. Votes for mesh infection detection methods varied but were based predominantly on clinical diagnosis with positive culture. Consequently, we devised a statement based on CDC criteria for wound infection; *'Purulent discharge from a wound containing a prosthetic mesh implant OR a positive culture from a chronic wound containing a mesh implant using a wound swab, fluid aspirate, or an explanted piece of mesh OR a positive culture from intra-operative fluid surrounding a mesh'*. Eleven panellists (73%) voted for 'clinical examination +/- CT scan' to detect hernia recurrence. When asked whether all inpatient post-operative complications should be recorded, 14 panellists (93%) suggested they should if part of trial follow up and data analysis. Overall, all panellists (100%) chose CT scanning to detect post-operative outcomes after PVH repair. Regarding follow-up duration, votes varied; 30 days, 1 year and 5 years received 14, 8, and 5 votes respectively, and were recommended by the steering committee as standardised follow-up durations.

After voting, panellists were asked whether their votes for detection methods for PVH variables could be applied to the same IVH variables. All panellists agreed to the same detection methods for IVH variables. As a caveat, the group added a cautionary note

regarding pre-operative CT scanning for trials of PVHs: While there was consensus regarding CT as the optimal detection method, panellists considered that trials should adopt low-dose targeted scanning to minimise radiation exposure where there was no clinical requirement for pre-operative CT. The finalised detection methods can be found in column 3 of the completed datasets, Table 1 and Table 2.

For our PROMs dataset, during the final round we asked panellists to vote on the timing of assessment. Fourteen panellists (93%) agreed that pre-operative baseline PROMs should be recorded. Concerning post-operative follow-up, again votes varied; however, 30 days, 1 year, and 5 years received 6, 10, and 6 votes respectively and the steering committee proposed these as standardised intervals for participant assessment.

Table 1.

Pre-operative Variables	Definition	Detection Method
Age	Years since birth	Age on the day of VH repair
Sex	Male/Female	Sex on the day of VH repair
Obesity/BMI	Kilograms/Height in meters squared	Calculated on the day of VH repair
COPD	Previous diagnosis of COPD	Taking repeat medications for COPD on the day of VH repair.
Smoker	EURAHS definitions (25): Never smoked, Ex-smoker (>12 months), Occasional smoker, Daily smoker No. pack years: No cigarettes/day x years of smoking / 20	Status selected on the day of VH repair
Diabetes (type I/II)	Previous diagnosis of type I/II DM.	Taking repeat medications for Diabetes on the day of VH repair.
Immunosuppression/Steroid use	Previous diagnosis requiring immunosuppression therapy.	Immunosuppression/steroids taken over the perioperative period.
ASA	American Society of Anaesthetists score.	Score on the day of VH repair
Hernia variables	**Definition**	**Detection Method**
No of hernia defects	No of defects in the anterior abdominal wall	CT*
Hernia width	Maximal defect width; if more than one defect, measure the width according EHS classification (12).	CT*
Loss of Domain	Written: A ventral hernia large enough such that simple reduction in its contents and primary fascial closure either cannot be achieved without additional reconstructive techniques or cannot be achieved without significant risk of complications due to the raised intra-abdominal pressure. Volume: Sabbagh Method: Hernia sac vol / Peritoneal cavity vol (33).	CT*
EHS score	EHS classification for Primary Ventral Hernias. Graded according to: Position; epigastric, umbilical, Spigelian, Lumbar. Maximal defect width; small <2cm, medium 2-4cm, large >4cm (12).	Clinical exam
Divarification	A separation of >2 cm is considered to be a rectus diastasis (34).	1. CT*
Reducible	Reducible Irreducible without skin changes Irreducible with skin changes Irreducible with bowel contents causing obstruction	1. Clinical exam +/- CT

Best imaging modality for pre-op assessment of hernia: CT*

Peri-operative variables	Definition	Detection Method
Lap/Open/Robotic (as treated, not ITT)	Mode of surgery	Intra-operative details
Mesh/suture repair	Method of repair	Intra-operative details
Mesh repair		
-Exact mesh name; material/type/brand	Document trade name. Type: biologic, biosynthetic, synthetic.	Intra-operative details
-Mesh fixation technique	Suture: absorbable/non-absorbable. Tacks: absorbable/non-absorbable	Intra-operative details
-Position of mesh – plane of insertion	ICAP nomenclature: Onlay, Anterectus, Inlay, Interoblique, Retrooblique, Retrorectus, Retromuscular, Transversalis Fascial, Preperitoneal, Intraperitoneal (35).	Intra-operative details
-Mesh size	Intraoperative measurement	Intra-operative details (cm^2)
-Bridging Vs Primary fascial closure	EHS definitions (25): Bridging: the anterior fascia of the hernia defect is not **completely** closed. Primary fascial closure: the anterior fascia of the hernia defect is **completely** closed	Intra-operative details
Suture repair		
-Suture type: absorbable/non-absorbable	Absorbable/Non-absorbable material used	Intra-operative details
VHWG grade	Four VHWG grades: Grade 1: Low risk; no history of wound infection, no co-morbidities. Grade 2: Co-morbid; smoker, obese, diabetic, immunosuppressed, COPD. Grade 3: Potentially contaminated; Previous wound infection, stoma present, violation of GI tract. Grade 4: Infected; Infected mesh, septic dehiscence (36).	Intra-operative details
CDC score	Four CDC grades: Grade 1: Clean; uninfected wounds with no inflammation, the alimentary tract is not entered. Grade 2: Clean-contaminated; operative wounds in which the alimentary tract is entered under controlled conditions, without spillage. Grade 3: Contaminated; operative wounds with a major breech in sterility or spillage from the alimentary tract, includes incisions where acute, non-purulent inflammation is encountered.	Intra-operative details

	Grade 4: Dirty; pre-existing infected operative wound prior to the start of the operation, includes mesh infection and enterocutaneous fistula (37).	
Post-operative outcomes	**Definition**	**Detection Method**
Wound infection (SSI)	CDC definition: A surgical site infection (SSI) is an infection that occurs after surgery in the part of the body where the surgery took place. Surgical site infections can sometimes be superficial infections involving the skin only. Other surgical site infections are more serious and can involve tissues under the skin or organs (38).	**Superficial**: Involves the skin and subcutaneous tissue, occurs within 30 days of surgery, AND; Patient has at least *one* of the following: -Purulent drainage from the superficial incision. -An organism identified by a positive culture. -Wound is deliberately opened by a surgeon or physician AND patient has at least one of these signs and symptoms localized pain or tenderness, localized swelling, erythaema, or heat. -Diagnosis of a superficial incision SSI by a surgeon or physician. **Deep**: Involves deep soft tissues of the incision, eg fascia or muscle, occurs within 30 or 90 days of surgery, AND; Patient has at least *one* of the following: -Purulent drainage from the deep incision. -A deep incision that spontaneously dehisces, or is deliberately opened by a surgeon or physician AND an organism identified by positive culture AND patient has at least one of the following fever (>38°C), localized pain, or tenderness. - an abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test. **Organ-space**: Involves any part of the body deeper than the fascial/muscle layers that was opened or manipulated during the surgery, occurs within 30 or 90 days of surgery, AND; Patient has at least *one* of the following: -Purulent drainage from a drain that is placed into the organ/space. -An organism identified by a positive culture. -An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test.

Surgical site occurrence (SSO)	Any SSI as well as wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tis- sue necrosis, wound serous drainage, chronic sinus drainage, localized stab wound infection, seroma, haematoma, exposed biological/synthetic mesh, myocutaneous anastomotic disruption, and development of an enterocutaneous fistula (39).	History and Clinical examination, medical records
Surgical site occurrence requiring procedural intervention (SSOPI)	SSOs requiring a procedural intervention, defined as wound opening or debridement, suture excision, percutaneous drainage, or mesh removal (40).	History and Clinical examination, medical records
Mesh infection	New definition: A chronic wound infection, wound sinus, or wound abscess in the location of a prosthetic mesh implant.'	Purulent discharge from a wound containing a prosthetic mesh implant OR a positive culture from a chronic wound containing a mesh implant using a wound swab, fluid aspirate, or an explanted piece of mesh OR a positive culture from intra-operative fluid surrounding a mesh.
Chronic pain	Pain lasting longer than 3 months post-surgery .	History and Clinical examination
Hernia recurrence	EHS definition: A protrusion of the contents of the abdominal cavity or preperitoneal fat through a defect in the abdominal wall at the site of a previous repair of an abdominal wall hernia (25).	Clinical examination +/- CT
Clavien-Dindo complication score	Clavien-Dindo Classification: Grade 1: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Includes drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. Includes wound infections opened at the bedside. Grade 2: Requiring pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are included. Grade 3a: Requiring surgical, endoscopic or radiological intervention not under general anaesthetic. Grade 3b: Requiring surgical, endoscopic or radiological intervention under general anaesthetic. Grade 4: Life-threatening complication requiring IC/ICU management. Grade 5: Death of a patient (41).	Post-operative hospital medical records

30 day re-operation rate	An abdominal operation under GA or Regional anaesthesia within 30 days of primary VH repair.	Post-operative hospital medical records

Best imaging modality for post-op assessment of hernia: CT.   Post op complications should be recorded at: 30 days, 1 year, 5 years

*This consensus group is not advocating a CT diagnosis for all patients that present to the general surgical clinic with a PVH. We are supporting and recommending the use of CT scanning for the measurement of pre-operative hernia characteristics/variables of participants entered into PVH interventional trials. If there is no clinical indication for a pre-operative CT scan then the trial participant should have a low-dose, targeted CT scan to obtain the pre-operative measurements (a radiation dose of approximately 4 CXRs). If the practicalities of a low dose, targeted CT are tricky then the patient should not be subjected to the radiation of a normal CT scan with intra-venous contrast.

Table 2.

Pre-operative Variables	Definition	Detection Method
Age	Years since birth	Age on the day of VH repair
Sex	Male/Female	Sex on the day of VH repair
Obesity/BMI	Kilograms/Height in meters squared	Calculated on the day of VH repair
COPD	Previous diagnosis of COPD	Taking repeat medications for COPD on the day of VH repair.
Smoker	EURAHS definitions (25): Never smoked, Ex-smoker (>12 months), Occasional smoker, Daily smoker No. pack years: No cigarettes/day x years of smoking / 20	Status selected on the day of VH repair
Diabetes (type I/II)	Previous diagnosis of type I/II DM.	taking repeat medication for diabetes on the day of VH repair.
Immunosuppression/Steroid use	Previous diagnosis requiring immunosuppression therapy.	Immunosuppression/steroids taken on the day of VH repair
ASA	American Society of Anaesthetists score.	Score on the day of VH repair
Hernia variables	**Definition**	**Detection Method**
Previous abdominal surgery/operations	No. of previous midline laparotomies: ___ No. of previous right sided subcostal incisions: ___ No. of previous right sided RIF incisions: ___ No. of previous right flank incisions: ___ No. of previous left flank incisions: ___ Other:	Clinical records
No previous VH repairs & details of previous mesh	No. of previous ventral hernia repairs at same site: ___ No. of previous meshes at same site:___ Previous planes used (ICAP nomenclature: Onlay, Anterectus, Inlay, Interoblique, Retrooblique, Retrorectus, Retromuscular, Transversalis Fascial, Preperitoneal, Intraperitoneal (35)): ___	Clinical records
Previous surgical site infection	Previous surgical site infection either following previous incision at hernia site or after previous hernia repair: Yes/No	Clinical records
Hernia width	Maximal defect width: if more than one defect, measure the width according to EHS classification (12).	CT
Loss of domain	Written: A ventral hernia large enough such that simple reduction in its contents and primary fascial closure either cannot be achieved without additional reconstructive techniques or cannot be achieved without significant risk of complications due to the raised intra-abdominal pressure.	CT

	Volume: Sabbagh Method: Hernia sac volume / Peritoneal cavity volume (33).	
Hernia defect area	New definition: 'The area of the hernia defect as the hernial sac passes through the abdominal wall muscles'	CT – Area calculated as an area of an ellipse (Area = a x b x π, a = major radius, b = minor radius)
EHS score	EHS classification for Incisional Ventral Hernias. Graded according to: Position; medial M1-5, Lateral L1-4, Recurrent incisional; yes/no, Maximum Defect Length, Maximal Defect Width, Width divided up into groups <4, 4-10cm, >4cm (12).	Clinical exam
Stoma present?	Abdominal wall ostomy present: Yes/No	Clinical records, intra-operative details
Previous component separation	Previous anterior component separation: Yes/No Previous transversus abdominis release: Yes/No	Clinical records, intra-operative details
Current mesh infection	New definition: 'A chronic wound infection, wound sinus, or wound abscess in the location of a prosthetic mesh implant'.	Purulent discharge from a wound containing a prosthetic mesh implant OR a positive culture from a chronic wound containing a mesh implant using a wound swab, fluid aspirate, or an explanted piece of mesh OR a positive culture from intra-operative fluid surrounding a mesh.

Best imaging modality for pre-op assessment of hernia: CT

Peri-operative variables	**Definition**	**Detection Method**
Pre-operative botox injection	Pre-operative intramuscular injection of Botulinum Toxin A into the abdominal strap muscles.	Pre-operative clinical details Total number of units given: Length of time pre-op: _____ (eg. 6 weeks)
Lap/Open/Robotic (as treated, not ITT)	Mode of surgery	Intra-operative details
Mesh/suture repair	Method of repair	Intra-operative details
Mesh repair		
-Exact mesh name; material/type/brand	Document trade name. Type: biologic, biosynthetic, synthetic.	Intra-operative details
-Mesh fixation technique	Suture: absorbable/non-absorbable. Tacks: absorbable/non-absorbable	Intra-operative details
-Position of mesh – plane of insertion	ICAP nomenclature: Onlay, Anterectus, Inlay, Interoblique, Retrooblique, Retrorectus, Retromuscular, Transversalis Fascial, Preperitoneal, Intraperitoneal (35).	Intra-operative details
-Mesh size	Intraoperative measurement	Intra-operative details (cm^2)
-Bridging vs Primary fascial closure	EHS definitions (25): Bridging: the anterior fascia of the hernia defect is not **completely** closed. Primary fascial closure: the anterior fascia of the hernia defect is **completely** closed.	Intra-operative details

-Mesh overlap	Mesh overlap area/defect area ratio: Circle: Overlap = $(\pi R^2 - \pi r^2)$, R = radius of mesh, r = radius of hernia defect Ellipse: Overlap = $\pi AB - \pi ab$. AB = major & minor radii of mesh, ab = major & minor radii of hernia defect (42).	Intra-operative clinical details/measured and calculated during the operation. Parameters calculate: mesh area & defect area If defect closed: just calculate mesh area.
Suture repair		
-Suture type – absorbable/non-absorbable	Absorbable/Non-absorbable material used	Intra-operative details
Type of component separation	Anterior component separation Transversus abdominis release	Intra-operative details
Concomitant GI bowel procedure	-Small bowel resection -Ileo-caecal resection -Colonic resection -Stoma formation -Other	Intra-operative details
VHWG grade	Four VHWG grades: Grade 1: Low risk; no history of wound infection, no co-morbidities. Grade 2: Co-morbid; smoker, obese, diabetic, immunosuppressed, COPD. Grade 3: Potentially contaminated; Previous wound infection, stoma present, violation of GI tract. Grade 4: Infected; Infected mesh, septic dehiscence (36).	Intra-operative details
CDC score	Four CDC grades: Grade 1: Clean; uninfected wounds with no inflammation, the alimentary tract is not entered. Grade 2: Clean-contaminated; operative wounds in which the alimentary tract is entered under controlled conditions, without spillage. Grade 3: Contaminated; operative wounds with a major breech in sterility or spillage from the alimentary tract, includes incisions where acute, non-purulent inflammation is encountered. Grade 4: Dirty; pre-existing infected operative wound prior to the start of the operation, includes mesh infection and enterocutaneous fistula (37).	Intra-operative details
Accurate reporting of intra-operative complications	-Enterotomy -Bleeding -Bladder injury	Intra-operative details

	-Systemic complications (eg cardiac) -Equipment malfunction Other	
Post-operative outcomes	**Definition**	**Detection Method**
Wound infection (SSI)	CDC definition: A surgical site infection (SSI) is an infection that occurs after surgery in the part of the body where the surgery took place. Surgical site infections can sometimes be superficial infections involving the skin only. Other surgical site infections are more serious and can involve tissues under the skin or organs (38).	**Superficial**: Involves the skin and subcutaneous tissue, occurs within 30 days of surgery, AND; Patient has at least *one* of the following: -Purulent drainage from the superficial incision. -An organism identified by a positive culture. -Wound is deliberately opened by a surgeon or physician AND patient has at least one of these signs and symptoms localized pain or tenderness, localized swelling, erythaema, or heat. -Diagnosis of a superficial incision SSI by a surgeon or physician. **Deep**: Involves deep soft tissues of the incision, eg fascia or muscle, occurs within 30 or 90 days of surgery, AND; Patient has at least *one* of the following: -Purulent drainage from the deep incision. -A deep incision that spontaneously dehisces, or is deliberately opened by a surgeon or physician AND an organism identified by positive culture AND patient has at least one of the following fever (>38°C), localized pain, or tenderness. - an abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test. **Organ-space**: Involves any part of the body deeper than the fascial/muscle layers that was opened or manipulated during the surgery, occurs within 30 or 90 days of surgery, AND; Patient has at least *one* of the following: -Purulent drainage from a drain that is placed into the organ/space. -An organism identified by a positive culture. -An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test.

Surgical site occurrence (SSO)	Any SSI as well as wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tis- sue necrosis, wound serous drainage, chronic sinus drainage, localized stab wound infection, seroma, haematoma, exposed biological/synthetic mesh, myocutaneous anastomotic disruption, and development of an enterocutaneous fistula (39).	History and Clinical examination, medical records.
Surgical site occurrence requiring procedural intervention (SSOPI)	SSOs requiring a procedural intervention, defined as wound opening or debridement, suture excision, percutaneous drainage, or mesh removal (40).	History and Clinical examination, medical records
Mesh infection	New definition: 'A chronic wound infection, wound sinus, or wound abscess in the location of a prosthetic mesh implant.'	Purulent discharge from a wound containing a prosthetic mesh implant OR a positive culture from a chronic wound containing a mesh implant using a wound swab, fluid aspirate, or an explanted piece of mesh OR a positive culture from intra-operative fluid surrounding a mesh
Chronic pain	ICD 11 classification of chronic pain. 'Pain lasting longer than 3 months post-surgery'.	History and Clinical examination
Hernia recurrence	EHS definition: A protrusion of the contents of the abdominal cavity or preperitoneal fat through a defect in the abdominal wall at the site of a previous repair of an abdominal wall hernia (25).	Clinical examination +/- CT
Clavien-Dindo complication score	Clavien-Dindo Classification: Grade 1: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Includes drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. Includes wound infections opened at the bedside. Grade 2: Requiring pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are included. Grade 3a: Requiring surgical, endoscopic or radiological intervention not under general anaesthetic. Grade 3b: Requiring surgical, endoscopic or radiological intervention under general anaesthetic. Grade 4: Life-threatening complication requiring IC/ICU management. Grade 5: Death of a patient (41).	Post-operative hospital medical records

30 day re-operation rate	An abdominal operation under GA or Regional anaesthesia within 30 days of primary VH repair.	Post-operative hospital medical records

Best imaging modality for post-op assessment of hernia: CT.   Post op complications should be recorded at: 30 days, 1 year, 5 years

Table 3: Patient reported outcomes (PROMs) for Interventional Trials assessing Ventral Hernia repair

EURAHS QoL score (25)**:**
Pain at hernia site:
1.Pain at rest (lying down) (0-10)
2.Pain during activities (walking, biking, sports) (0-10)
3.Pain felt during the last week (0-10)
Restrictions of activities because of pain or discomfort at the site of the hernia:
4.Restriction from daily activities (inside the house) (0-10)
5.Restriction outside the house (walking, biking, driving) (0-10)
6.Restriction during sports (0-10)
7.Restriction during heavy labour (0-10)
Cosmetic discomfort:
8.Shape of abdomen (0-10)
9.Site of hernia (0-10)
SF12 (32)**:**
10.In general, would you say your health is: Excellent, Very good, Good, Fair, Poor
11.Moderate activities, such as moving a table, getting dressed, cooking, bowling, or playing golf: Yes, Limited a lot, Yes, limited a little, No, not limited at all.
12.Climbing several flights of stairs: Yes, Limited a lot, Yes, limited a little, No, not limited at all.
13.Due to physical health problems over the past 4 weeks: Have you accomplished less than you would like? Yes/No
14. Due to physical health problems over the past 4 weeks: Have you been limited in the kind of work/other activities? Yes/No
15.Due to emotional health problems over the past 4 weeks: Have you accomplished less than you would like? Yes/No
16.Due to emotional health problems over the past 4 weeks: Have you been limited in the kind of work/other activities? Yes/No
17.During the past 4 weeks, how much did pain interfere with your normal work? Not at all, A little bit, Moderately, Quite a bit, Extremely
18.Over the past 4 weeks: Have you felt calm and peaceful? All of the time, Most of the time, A good bit of the time, Some of the time, A little of the time, None of the time.
19. Over the past 4 weeks: Did you have lots of energy? All of the time, Most of the time, A good bit of the time, Some of the time, A little of the time, None of the time.
20.Over the past 4 weeks: Have you felt down hearted and blue? All of the time, Most of the time, A good bit of the time, Some of the time, A little of the time, None of the time.
21.Over the past 4 weeks: how much has your physical or emotional problems interfered with your social activities? All of the time, Most of the time, A good bit of the time, Some of the time, A little of the time, None of the time.
Expert patient questions:
22.My mental health currently is (answers: awful, poor, fair, good, very good, excellent)
23.My sexual activity currently is (answers: awful, poor, fair, good, very good, excellent)
24. Having the operation was the right decision (answers: strongly agree, agree, neither agree or disagree, disagree, strongly disagree)
25. I would go for the same choice if I had to do it over again (answers: strongly agree, agree, neither agree or disagree, disagree, strongly disagree)

PROMS should be recorded at: 30 days, 1 year, 5 years

Methodology Criteria for Primary and Incisional VH Interventional Trials
General
Funding
Protocol
Registered Trial
Ethical Approval
Introduction
Background and rationale
Primary aim or objective
A pre-specified referenced hypothesis
Method
Randomised trials
Method of generating random allocation sequence
Method of implementing the random allocation
Blinding of the participant to the intervention received
Blinding of the care providers
Non-randomised trials/studies
Explain how the study groups/arms were selected, avoiding selection bias
All Interventional (Randomised and non-Randomised Interventional Trials)
Description of trial design
Trial setting (single/multicentre),names of centres where data will be collected
Describe the intended periods of recruitment and follow up
Description of the interventions, with sufficient detail to allow replication
Defined and referenced primary outcome, with well described methods for detection and measurement
Secondary outcome measures, defined and referenced, with described methods for detection and measurement
Power/Size calculation
Specific inclusion/exclusion criteria
Reports eligibility and number included
Blinding of the outpatient assessor/independent blinded outpatient assessor
Describe methods of follow-up
Results
Recruitment dates - Start date?, Finish date, End of follow-up date
Participant flow chart - for each group showing the no. of participants meeting inclusion criteria, then no. included, no. receiving the intended treatment, no. analysed for primary outcome (includes explanations for participant losses)
A table showing baseline characteristics/pre-operative variables between each group
Report all harmful events in each group
Deviations from the intended intervention reported?
Statistics
Length of follow-up reported

Details on Per Protocol analysis or Intention to Treat analysis
Number of participants with missing data
Statistic methods for comparing the groups; for primary and secondary outcomes
Additional methods for subgroup analyses and adjusted analyses
Reports adjusted analysis (with adjustment factors clearly listed)
Explains how missing data will be addressed
Reports estimated effect size with 95% confidence intervals
<u>Discussion</u>
Summarises key results with reference to study objectives
Trial limitations, addressing sources of potential bias, imprecision
Interpretation consistent with results, balancing benefits and harms
Generalisability of the study results

Table 4. Forty methodology recommendations for PVH and IVH interventional trials. These criteria were devised using existing methodology tools; Downs & Black (19), ROBINS-I (20), CONSORT statement (21), STROBE (22), TIDieR checklist (23), and the Newcastle Ottawa Scale (24).

Discussion

Informed by systematic review and via expert consensus, we have constructed minimum datasets for interventional trials of primary and incisional VH. Not only have two previous systematic reviews (10,11) illustrated a requirement for minimum datasets, so too have calls from hernia surgeons, asking that a 'common language' be used for outcome reporting and research. Indeed, Debord et. al. called for, "an international task force to establish the definitions for wound events after hernia repair"(43). Our work has used an international group to both standardise post-operative wound events, and define pre-operative patient variables, hernia characteristics, reported peri-operative variables, post-operative outcomes, and patient reported outcomes for VH trials. We have also included trial methodology criteria to try and create a 'handbook' or 'manual' to help and facilitate those researchers planning VH trials. A greater wealth of standardised data will facilitate pooling and comparisons, including meta-analysis, so that new knowledge regarding optimal treatment options and outcome predictors has a more substantial evidence base.

We are aware this article will challenge investigators because it will demand they adhere to the stipulated variables and definitions. Adhering to the intricacies of variable definitions and detection methods may appear laborious. However, our argument is sound; hernia scientists must collect accurate data that is comparable across studies, centres, and countries. Much of the current difficulties in herniology stem from poorly defined variables and heterogenous data. If the hernia community is to discover which variables (patient, hernia, or peri-operative) are most predictive of outcomes and which treatments are most beneficial, accurate and comparable data must be collected. We hope that by providing all variable

definitions and detection methods in one manuscript will simplify understanding and adherence to these minimum datasets.

The group has recommended CT scanning as the optimal modality for pre-operative hernia assessment including trials of PVH. This recommendation maybe seem problematic as it relies on CT scanning being available for research, which competes with clinical demand, and scanning involves radiation exposure, an issue high-lighted by three panellists. However, it is well-established that CT scanning is superior and more reproducible than clinical examination when attempting to diagnose hernia and its location, morphology, and content, and our recommendations are made in the setting of prospective interventional trials. Because patient safety is paramount, we advocate low-dose targeted and adaptive scanning in the absence of a defined clinical indication for pre-operative CT.

It is important readers understand our work is a consensus. Accordingly, not all panellists agreed with every variable, definition, or detection method. For example our chosen definition for loss of domain was rejected by one panellist stating, '*this would mean that every patient where you perform an anterior component separation or a transversus abdominis release there is loss of domain, I would tend to disagree with that; for me the cut-off is 20%* (Sabbagh)*'*. Our definition for loss of domain doesn't stipulate a volumetric cut-point because, as yet, a generally accepted threshold to discriminate between significant and insignificant loss of domain does not exist; Only a written definition has been established (33). Another definition prompting ample group feedback was the definition of mesh overlap. We settled on a ratio, the mesh overlap:defect area ratio, which overlooks several important factors. Firstly, it assumes that both the implanted mesh and the hernial defect are either circular or elliptical, and does not account for either a rectangular mesh or multiple defects.

In this situation, the data collectors (investigators) should still use basic mathematics to divide the mesh area by the defect(s) area, as the forces causing and preventing eventration are still proportional to both these areas (42). Secondly, it assumes a bridging repair. If the defect is closed completely, the defect area and eventration force become zero (Force = Pressure x Area (42)), and mesh overlap area to defect area ratio becomes infinity. In such cases, the group advises that investigators simply document mesh area; if a closed wound breaks down then the value of mesh area represents the force of eventration resistance and may be inversely proportional to hernia recurrence. Lastly, mesh porosity was not a variable chosen for either dataset, but was discussed at our group meeting. Panellists were aware that porosity is an important variable, which has been shown to correlate with outcomes such as mesh infection (44), chronic pain (45), bacterial load (46) and surgical site occurrence (47) . However, the group felt that a separate variable for porosity was unnecessary because it was imperative the exact name and type of mesh was recorded. Given this, porosity could be deduced.

Hernia academics reading this manuscript will recognise that its contents bear resemblance to two prior articles. The first is the published outcomes of a 2012 consensus meeting in Palermo, which made recommendations for reporting outcomes for abdominal wall repair and also advised hernia surgeons regarding study design (48). The second is an article from the European Hernia Society containing a dataset to launch the European registry for abdominal wall hernias (EuraHS) (25), also from 2012. In essence, our current work updates both of these articles. As new knowledge emerges and new definitions are established (33,35), updates of standardised trial design and data accuracy are required to drive continuous improvement (49). In addition, although our article aims to improve interventional trial design and trial data quality, two international hernia societies (the British

Hernia Society and the European Hernia Society) have already expressed interest in using our datasets to create and launch their new hernia registries. All the authors would encourage this.

In summary, using a panel of expert hernia surgeons and patient advocates, we have produced minimum datasets for primary and incisional hernia interventional trials, a set of standardised patient reported outcomes, and a checklist of methodology criteria, with the aim of improving trial design and resultant research quality. We hope this "manual" will aid hernia researchers intending to perform such trials. If trials collect consistent, well defined data, comparison of their results across centres and countries will be facilitated, with the aim of improving investigation of the effect of peri-operative variables on patient and surgical post-operative outcomes.

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