ITEMS TO INCLUDE WHEN REPORTING CLINICAL RESEARCH

CHECKLIST I: CLINICAL TRIALS

Item		Description
Title	☐	Identify **study type** (randomised, observational, cohort, case-control, cross-sectional)
	☐	Identify **area of focus** (e.g. disease, exposure/intervention)
Authors	☐	Contact details for the corresponding author
Introduction		***Why did you start?***
	☐	Scientific/medical background
	☐	Rationale –why is this study needed?
	☐	Specific objectives, hypothesis
Trial design		***What is it?***
	☐	Description of the trial design (e.g. parallel, cluster, non-inferiority, cohort, case-control, cross-sectional)
	☐	State whether prospective or retrospective
	☐	State whether single-center or multi-center
Methods		***What did you do?***
Ethical approval	☐	**Give IRB oversight number**, and registration number (if applicable)
Participants	☐	Eligibility criteria for participants (inclusion/exclusion)
	☐	Settings where the data were collected
	☐	Relevant dates, time periods (recruitment, exposure, follow-up, data collection)
	☐	Describe sources and selection methods for participants;
	☐	If applicable: Describe methods of case ascertainment; control selection;matching criteria; number of exposed vs unexposed; etc.
Interventions (if applicable)	☐	Interventions intended for each group
Outcome	☐	Clearly defined **primary and secondary outcomes**
Bias	☐	Describe efforts to address potential sources of bias (e.g. randomization, blinding for RCTs, matching criteria for observational studies; controls)
Results		***What did you find?***
Participants	☐	Number of participants at each stage; reasons for non-participation
Descriptive data	☐	Characteristics of participants (demographic, clinical, etc.)
	☐	Information on interventions/exposures, potential confounders
Numbers analysed	☐	Number of participants analysed in each group
Outcome	☐	Outcome result for each group and the estimated effect size and its precision
Harms	☐	Important adverse events or side effects
Conclusions		***What does it mean?***
	☐	Summarise key results with reference to study objectives
	☐	Limitations (potential sources of bias, imprecision)
	☐	Generalizability (external validity, applicability) of trial findings
	☐	Interpretation consistent with results, balancing benefits and harms, considers other relevant evidence
Funding and Conflicts of interest	☐	Source of funding and other support (e.g. supply of device, drugs) if applicable
	☐	State any conflicts of interest

CHECKLIST II: CASE SERIES, CHART REVIEWS

Item	Description
Title	☐ Identify **study type** case series, chart review) ☐ Identify **area of focus** (e.g. disease, exposure/intervention, procedure)
Authors	Contact details for the corresponding author
Introduction	***Why did you start?***
	☐ Scientific/medical background, summary of what is currently known ☐ Rationale –why is this study needed? ☐ Unifying theme (e.g. common disease, exposure, intervention and outcome, etc.)
Methods	***What did you do?***
Ethical approval	☐ Was IRB approval required? If so give number. If not, provide justification
Study design	☐ State whether prospective or retrospective ☐ State whether cases are consecutive or non-consecutive ☐ State whether single-center or multi-center
Participants	☐ Settings, location where data were collected ☐ Eligibility criteria (inclusion/exclusion) ☐ Relevant dates, time periods ☐ Describe sources and selection methods for participants; ☐ Describe methods and duration of follow-up ☐ Relevant characteristics of participants (comorbidities, tumor staging, etc.) ☐ Describe pre-intervention considerations
Personnel	☐ Describe who performed the procedures (operator experience, prior training, specialization, etc)
Interventions	☐ Type of interventions and justification of treatment offered (pharmacological, surgical, physiotherapy, psychological, preventative etc.) ☐ Describe concurrent treatments (e.g. antibiotics, VTE prophylaxis, PO etc) ☐ For medical devices- specify manufacturer, model
Peri-interventions	☐ Administration protocol (what, when, where, how) e.g. surgery; anaesthesia, patient position, use of tourniquet and other relevant equipment, preparation used, sutures, devices, surgical stage (1 or 2 stage, etc). ☐ Pharmaceutical therapies should include drug, formulation, dose, strength, route, duration
Post-interventions	☐ Post-operative instructions and place of care. ☐ Relevant follow-up procedures; diagnostic and other test results. Future surveillance requirements (e.g. imaging surveillance of endovascular aneurysm repair (EVAR), clinical exam; ultrasound, etc.)
Results	***What did you find?***
Participants	☐ Number of participants; characteristics, summary measures
Interventions	☐ Changes during the course of the case series (has it evolved, been tinkered with, learning etc.) ☐ Comment on learning curves for new methods, devices

Conclusions		***What does it mean?***
	□	Summarise key results with reference to study objectives
	□	Interpretation consistent with results
	□	Discussion of the relevant literature – how do outcomes compare with established therapies, current gold standard (if it exists)?
	□	Implications for clinical practice
	□	Limitations (potential sources of bias)
Funding and conflicts of interest	□	Source of funding and other support (e.g. supply of device, drugs) if applicable
	□	State any conflicts of interest

CHECKLIST III: QUALITY IMPROVEMENT

Item		Description
Title	□	Identify as a **quality improvement initiative**
	□	Identify **area of focus** (quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, equity)
Authors	□	Contact details for the corresponding author
Introduction		***Why did you start?***
	□	Problem description
	□	Summary of what is currently known
	□	Rationale for problem (frameworks, models, concepts, theories), development of intervention, reasons why intervention is expected to work
	□	Specific aims
Methods		***What did you do?***
Ethical oversight	□	Was IRB approval required? If so give number. If not, provide justification
Context	□	Describe contextual elements judged important at onset
Interventions	□	Describe interventions in enough detail to allow replication
	□	How was the impact of the intervention assessed?
	□	How was it determined that observed outcomes resulted from the intervention?
Personnel	□	Specifics of team involved in the work
Process measures	□	What factors were used to measure intervention and outcomes? Include operational definitions, validity, reliability
	□	What factors were measured to assess success/failure/efficiency/ cost
	□	What qualitative and quantitative methods were used to make inferences from the data?
Results		***What did you find?***
Intervention process	□	Time-line diagram, flow chart etc. describing initial steps of intervention and modification over time
Process measures	□	Describe measures and outcomes, summary statistics if applicable
Contextual elements	□	Describe elements interacting with intervention
Associations	□	Describe associations between outcomes, interventions and relevant contextual elements
Unintended consequences	□	Important unexpected events, benefits, problems, failures, costs, associated with the intervention
Conclusions		***What does it mean?***
	□	Summarise key findings and how they relate to rationale and specific aims
	□	Discussion of the relevant literature, comparison of findings
	□	Impact on people and systems, costs and strategic trade-offs
	□	Limitations (potential sources of bias, imprecision)
	□	Generalisability (external validity, applicability, sustainability potential to be replicated elsewhere)
	□	Implications for practice
	□	Suggested next steps
Funding and conflicts of interest	□	Source of funding and other support if applicable
	□	State any conflicts of interest

CHECKLIST IV: EDUCATIONAL INITIATIVES

Item	Description
Title	☐ Identify **type of study** (educational, teaching) ☐ Identify **area of focus**
Authors	☐ Contact details for the corresponding author
Introduction	***Why did you start?*** ☐ Background, explanation of rationale ☐ Describe educational theory, concept or approach used in the intervention ☐ Specific learning objectives, hypothesis
Methods	***What did you do?***
Ethical oversight	☐ Was IRB approval required? If so give number. If not, provide justification
Materials (WHAT)	☐ Describe the specific educational materials: (a) used in training the intervention providers; (b) provided to learners
Study design	☐ Trial type (randomised controlled trial, cohort, before-after, qualitative, etc.)
Content	☐ Describe teaching/learning strategies (e.g. tutorials, lectures, online, etc.) ☐ Describe learning objectives, outcomes ☐ Content of evidence-based practice included in intervention (if applicable)
Personnel (WHO)	☐ Participants: Describe ☐ relevant demographics, how recruited ☐ any incentives or reimbursements provided to learners ☐ how participants were assessed and by whom ☐ Instructors: Describe ☐ professional standing, ☐ teaching experience/expertise/ ☐ study-specific training
Delivery (HOW)	☐ **Delivery** (face-to-face, classroom, self-directed, web-based etc.) ☐ **Individually-based or group** (if group, describe ratio of learners:instructors) ☐ **Delivery assessment:** Processes used to determine if materials and educational strategies were delivered as planned
Environment (WHERE)	☐ **Physical learning space** (conference, lecture theatre, hospital ward, bedside, community, etc.)
Schedule (WHEN, HOW MUCH)	☐ **Schedule:** Describe **number of sessions, frequency, timing, duration**
Evaluation (How did you know it worked?)	☐ Methods of assessment used for the learners (test, questionnaire, etc) ☐ Outcome measures (qualitative, quantitative, score, Likert scale, etc.) ☐ Methods of analysis ☐ Cost assessment
Results	***What did you find?***
Participants	☐ Describe learner attendance, number of participants recruited, completing, dropouts
Outcomes	☐ Summarise outcomes with measures of precision
Changes	☐ Planned and unplanned changes to implementation of intervention
Conclusions	***What does it mean?*** ☐ Summarize key results with reference to study and learning objectives

	□ Limitations (potential sources of bias, imprecision, barriers to implementation) □ Generalizability (external validity, applicability) of study findings □ Interpretation consistent with results, consider other relevant evidence □ Potential cost:benefit
Funding, conflicts of interest	□ Source of funding and other support (e.g. supply of device, materials, etc.) if applicable □ State any conflicts of interest