



AmSECT 2024 Pediatric and Congenital Perfusion Guidelines

The Clinical Dashboard & Operational Framework

Version:

2024 Update

Scope:

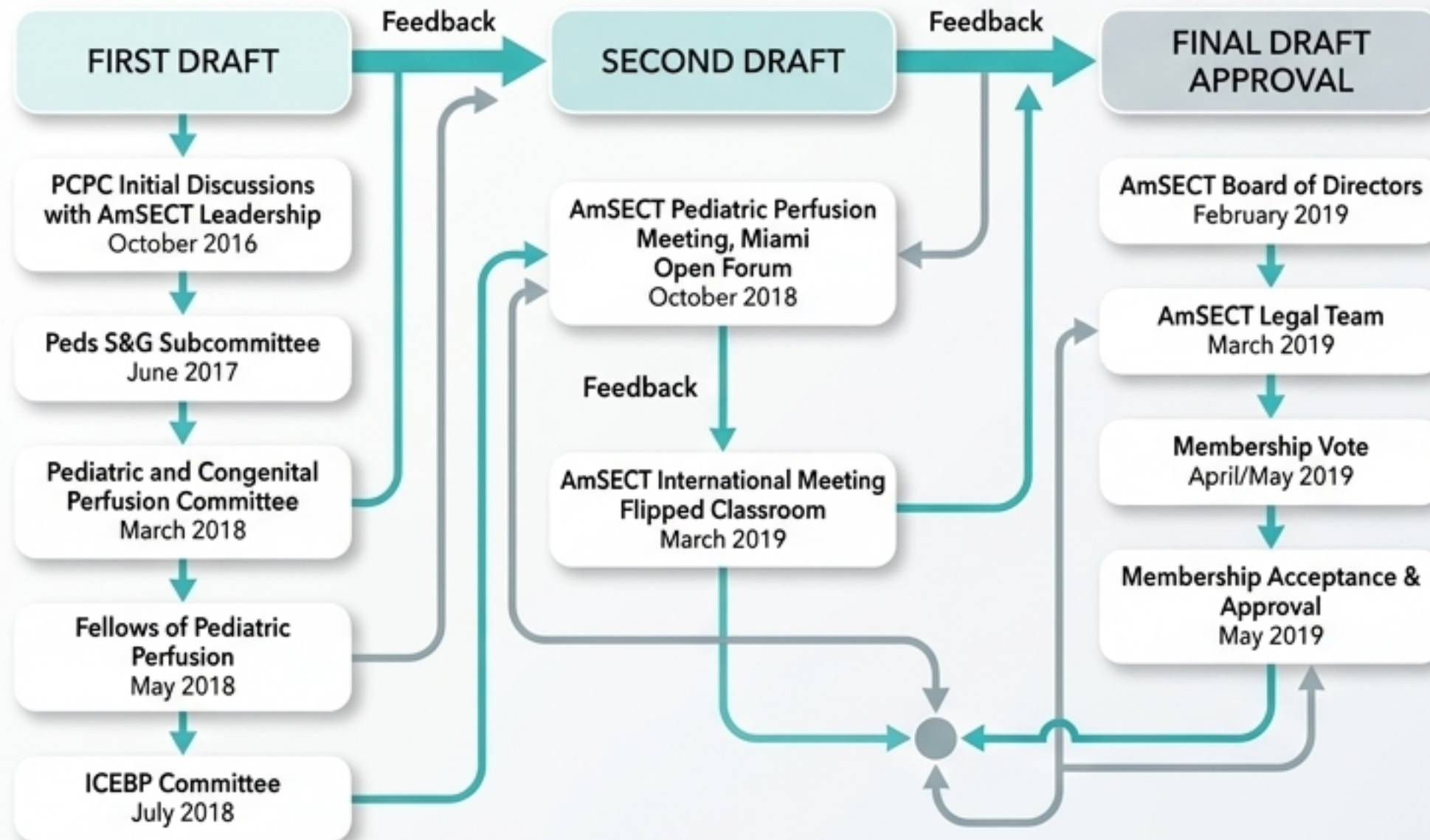
Extracorporeal Support

Standards:

22 Indexed Linear Protocols

THE 2024 DELTA: EVOLUTION OF CLINICAL STANDARDS

THE HISTORICAL CONTEXT



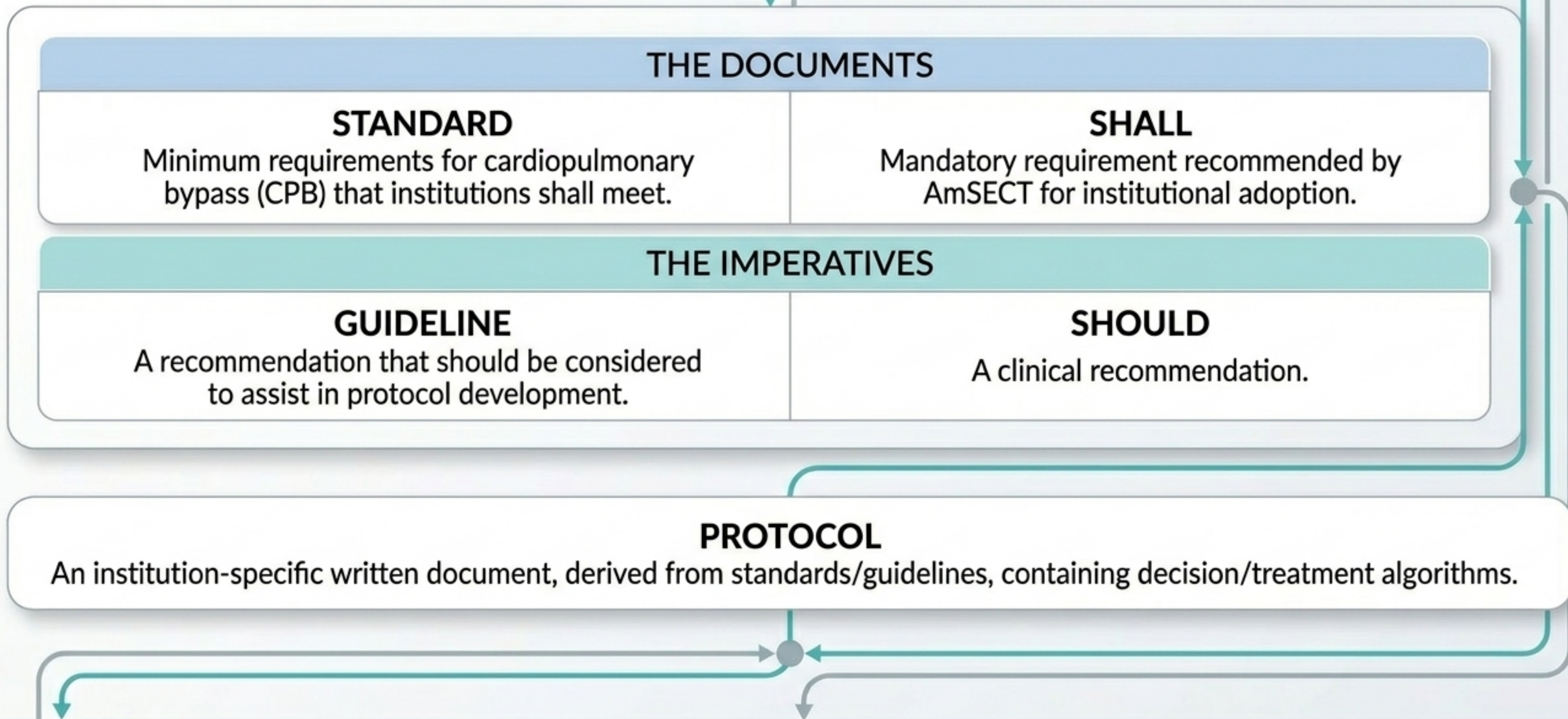
Tracing the evolution from the 2019 baseline (J. Extra Corporeal Technol. 2020) to the 2024 operational update.

KEY ADDITION

CRISIS MANAGEMENT (STANDARD 22)

- ⚠️ • Incorporates modernized references.
- ⚠️ • Enhances protocol alignments.
- ⚠️ • Formalizes emergency readiness parameters.

LEXICON & COMPLIANCE: NAVIGATING THE GUIDELINES



THE 4-PILLAR OPERATIONAL FRAMEWORK

Pillar 1: Institutional Foundations

- Protocols (1)
- Staffing (18)
- Duty Hours (19)
- QA (20)
- Maintenance (21)
- Crisis Management (22)

Pillar 2: Team Readiness & Execution

- Qualifications (2)
- Communication (3)
- Records (4)
- Checklists (5)
- Standby Readiness (17)

Pillar 3: The Circuit & Safeguards

- Safety Devices (6)
- Circuitry (12)

Pillar 4: Patient Physiology & Management

- Monitoring (7)
- Anticoagulation (8)
- Gas Exchange (9)
- Blood Flow (10)
- Blood Pressure (11)
- Priming (13)
- Protamine (14)
- Blood Mgmt (15)
- Fluid Mgmt (16)

Protocol Development (Std 1)

- Every standard shall have an institution-specific operating protocol.
- Must be approved by Chair of Cardiac Surgery / Director of Perfusion.
- Reviewed and revised annually.
- Emergency protocols must be accessible.

Quality Assurance (Std 20)

- Mandatory participation in QA/safety reporting.
- Data shall be collected via a clinical registry to advance quality and drive improvement projects.

Maintenance & Equipment (Std 21) Maintenance & Equipment (Std 21)

- Preventive maintenance performed by qualified manufacturer/Bio-Med techs.
- Must follow protocols for equipment failures and regulatory notices (recalls/warnings).
- Backup supplies must be readily available.

Staffing & On-Call (Std 18)

$$n \text{ (active ORs)} + 1 \text{ (staff)} = \text{Minimum Safe Staffing}$$

On-call perfusionist must be clinically ready within **60 minutes** for emergencies.

Duty Hours (Std 19)


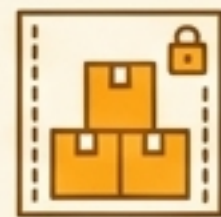

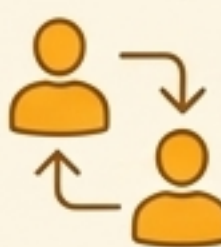
Maximum 16-hour consecutive work period.



Minimum 8 hours rest period for every 16-hour consecutive work period.

Crisis Management (Std 22 - NEW)

Actionable plans required for **unforeseen prohibitions** of standard duties.

 <p>Identify Alternate Vendors (Supply Chain)</p>	 <p>Alternate Storage & Staging Areas</p>
 <p>Patient Evacuation Procedures</p>	 <p>Staff Repurposing Roles</p>

Qualifications (Std 2)

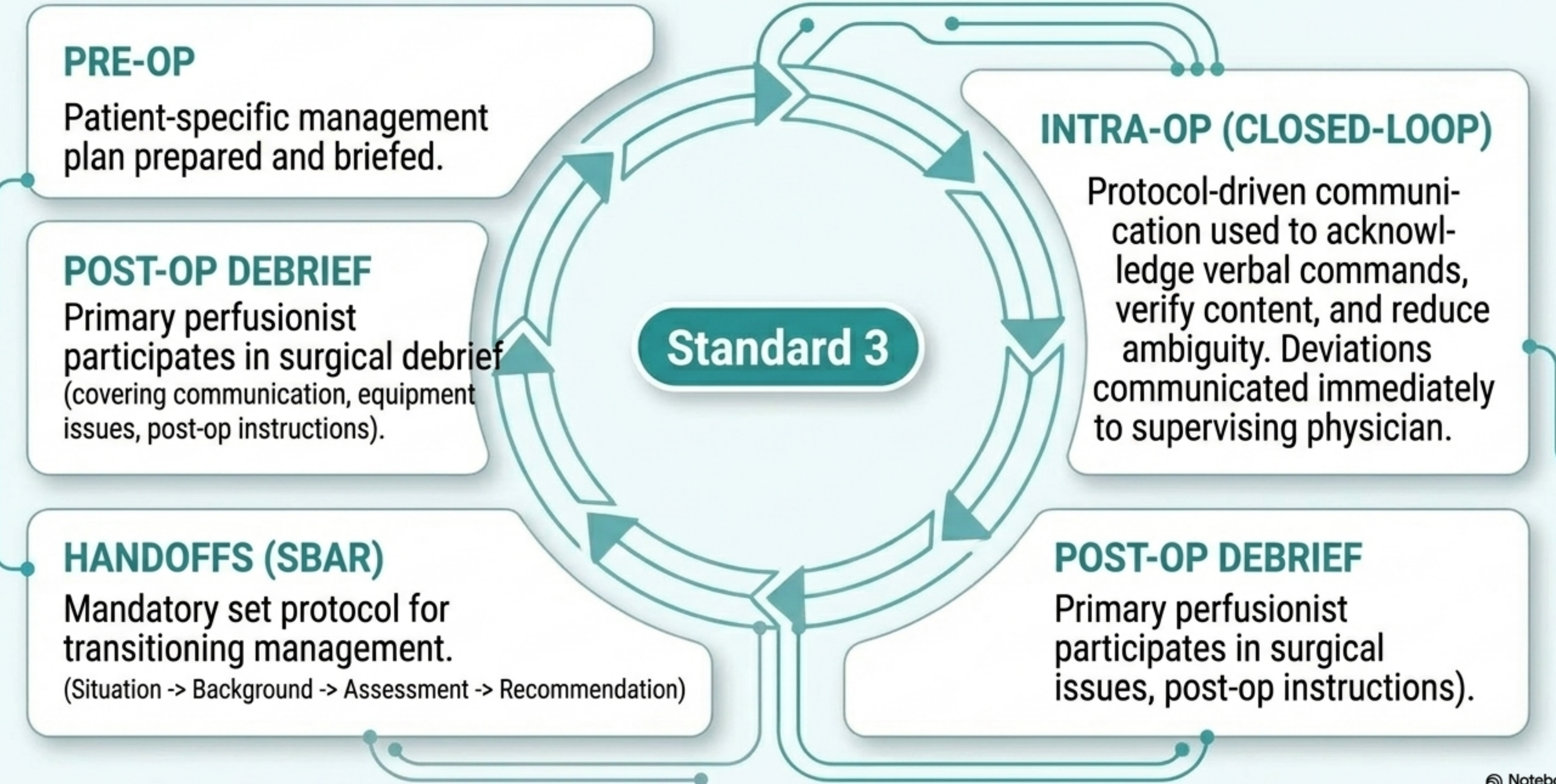
Long-term Perfusionist Requirements

- ✓ • Board certification (ABCP) or equivalent.
- ✓ • Annual competency assessment.
- ✓ • Annual perfusion-related CEUs (pediatric preferred).
- ✓ • Onboarding outlines for new hires including hazardous materials training.

Standby Readiness (Std 17)

Immediate Situational Prerequisites

- ✓ • Required for elevated-risk non-CPB procedures.
- ✓ • 1 dedicated perfusionist assigned.
- ✓ • Heart-lung machine sterile set-up ready.
- ✓ • Aseptic assembly per protocol.
- ✓ • Level of readiness determined via surgical team consultation.

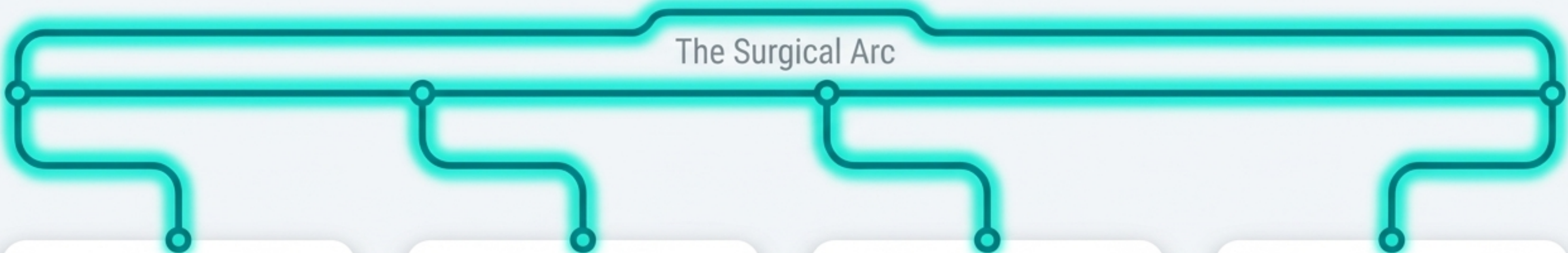


PILLAR 2 | THE PERFUSION CHECKLIST TIMELINE

[TAG: PROTOCOL]

Methodology (Std 5): Two-person "Read-Verify" method required. Checklist is part of permanent record.

The Surgical Arc



Setup

Patient ID, Sterility,
Pump occlusion/rotation,
Electrical/Battery, Gas
source

Pre-Bypass

Lines clamped,
debubbled, alarms
engaged, heparin
time/dose confirmed,
confirmed, ACT checked

Cessation/Termination

Announce termination,
lines clamped, shunt
closed, suction off

Post-Bypass / Emergent Restart

Emergent restart
requires specific re-
verification of heparin,
debubbling, gas flow, and
alarms

PILLAR 2 | THE PERMANENT PERFUSION RECORD

[TAG: DOCUMENTATION]

Requirement (Std 4): Maintained as part of permanent medical record. Must include signatures of primary and relief perfusionists. Open text/factual commentary on verbal orders recommended.

Demographics (App A)

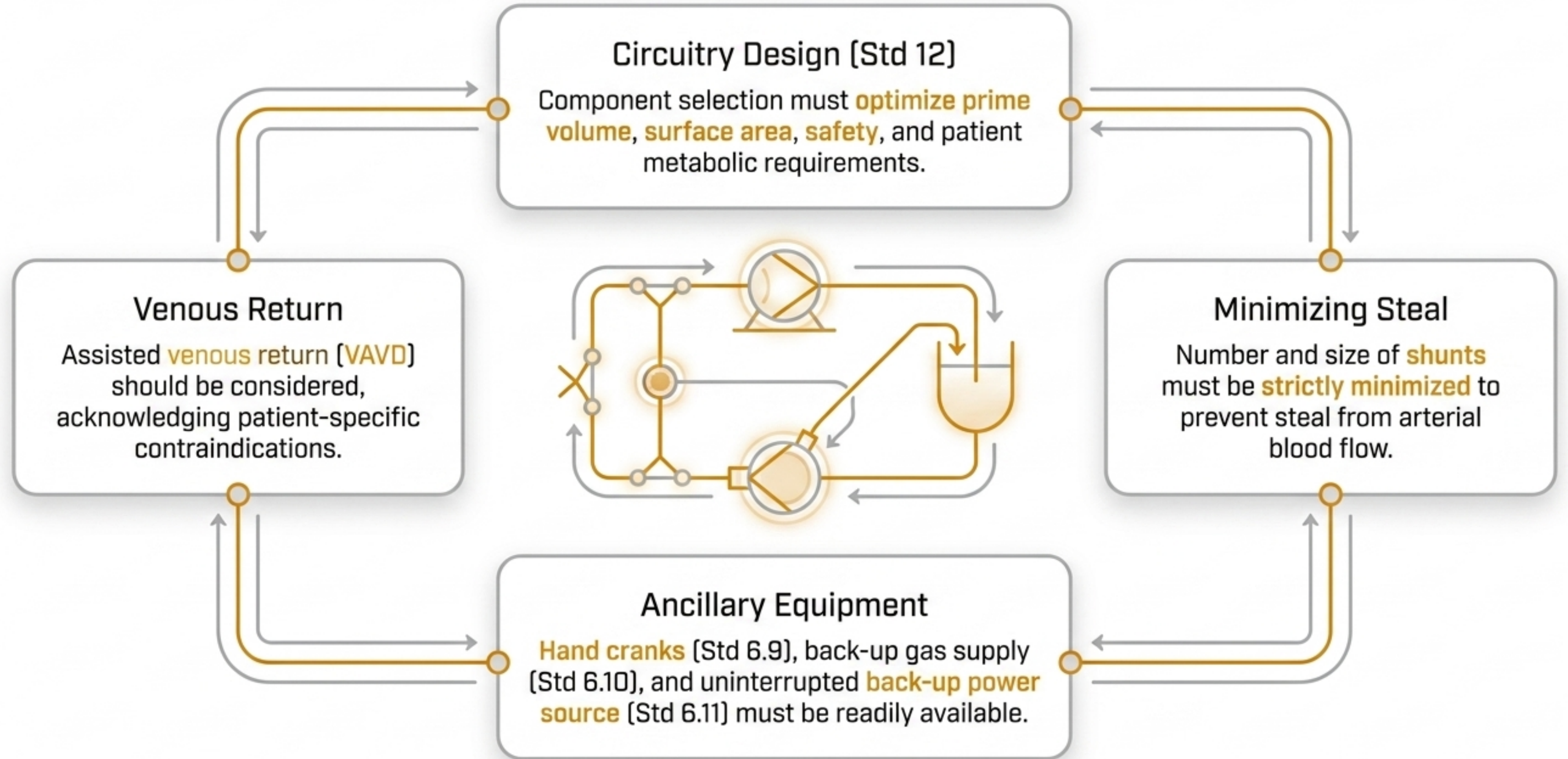
BSA, Blood Type, Lab Data (Hgb, WBC, Platelets, aPTT), Allergies, Risk Factors.

Procedure & Personnel (App B)

Primary/relief delineation, Surgeons, Anesthesiologists.

Equipment & Disposables

Unique IDs for Heart Lung Machine, Cell Salvage, Heater/Cooler. Lot numbers for oxygenators, reservoirs, filters, cannulas.



PILLAR 3 | MANDATORY SAFETY DEVICE SCHEMA

[TAG: EQUIPMENT]

[TAG: ALERT]

1. PRESSURE MONITORING

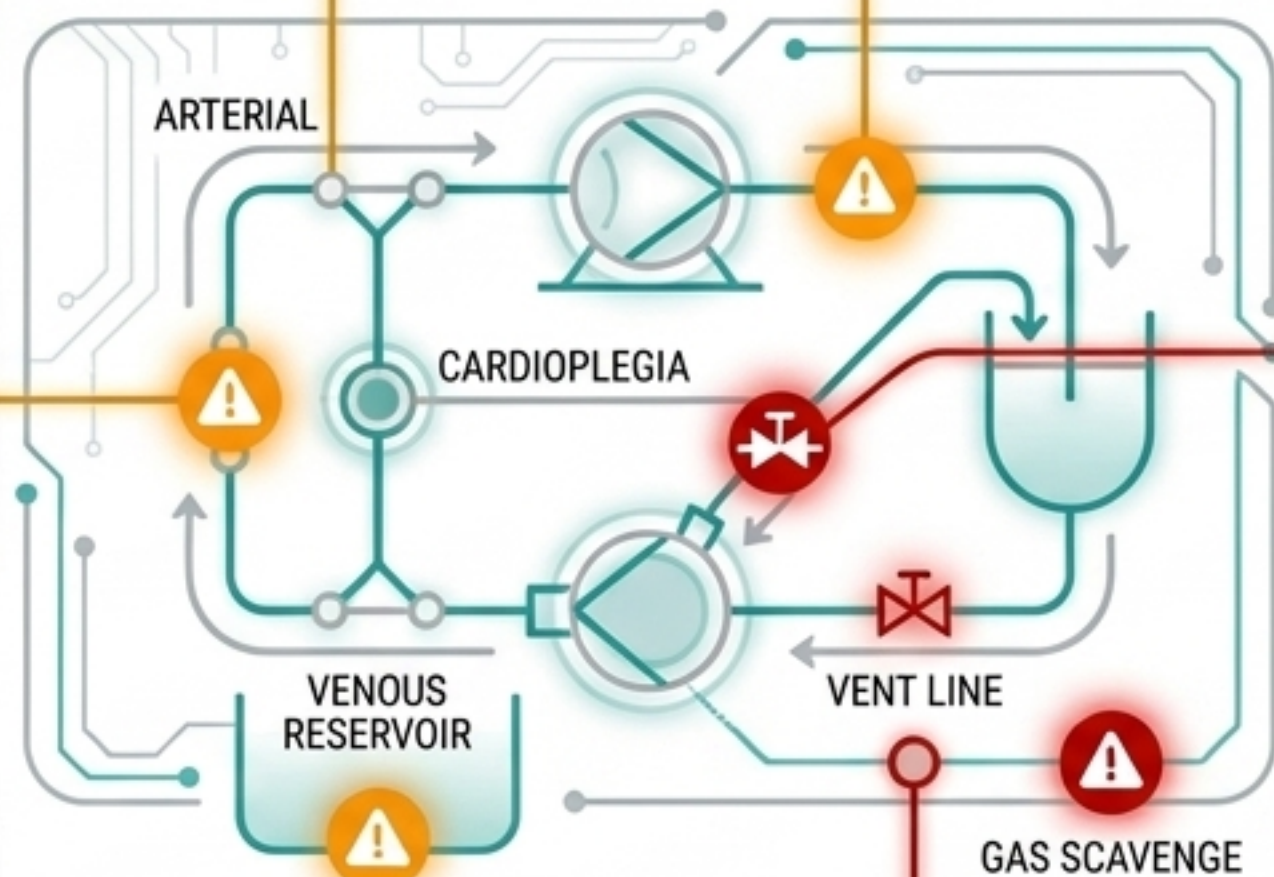
At arterial line, cardioplegia delivery, and venous reservoir. Must servo-regulate pump or interrupt flow. Audible/visual alarms.

2. BUBBLE DETECTOR

Gross/macro detector to control arterial/cardioplegia pump. Audible/visual alarms.

3. LEVEL SENSOR

On hard-shell reservoir (soft-shell recommended). Servo-regulated to interrupt flow.



4. TEMPERATURE SENSOR

On arterial outflow from oxygenator. Audible/visual alarms for high temps.

5. RETROGRADE FLOW AVOIDANCE

For centrifugal pumps (one-way valves, hard stop detents, electronic clamps).

6. GAS/SCAVENGE SAFEGUARDS

One-way valve in vent line. Anesthetic gas scavenge line if inhalation agents used. Disconnect detection alarms recommended.

CONTINUOUS (WITHOUT CEASING)

- Patient arterial blood pressure & Arterial line pressure.
- Arterial blood flow (measured distal to shunts).
- Hematocrit (or hemoglobin).
- Venous & Arterial oxygen saturation.
- Cerebral & Somatic oximetry.
- Blood gas (via continuous inline monitors).

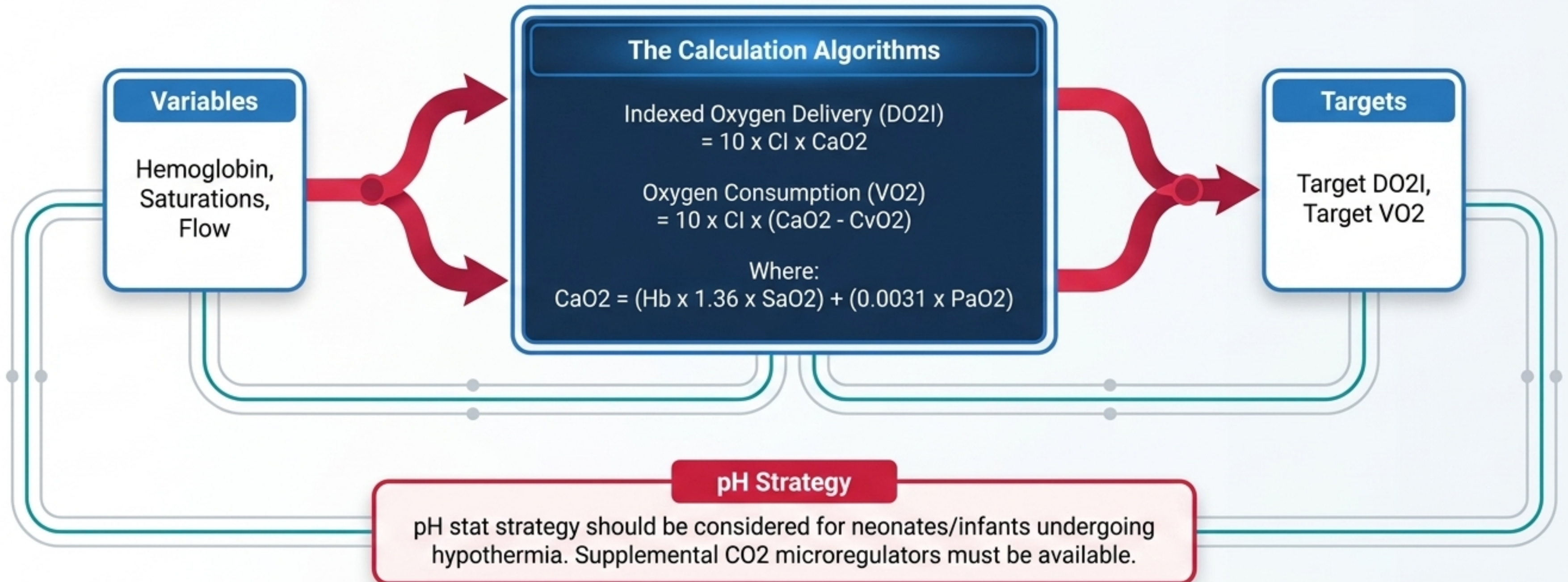
CONTINUAL (RECURRING FREQUENTLY)

- Patient core & device temperatures (Heart-lung machine, Heater/Cooler).
- Cardioplegia dose, temp, delivery, pressure, ischemic intervals.
- Blood gas analysis (via regular point-of-care intervals).
- Blood gas analysis (via pepertraly).
- Oxygen fraction and gas flow rates.
- Venous occluder occlusion percentage.

PILLAR 4 | THE GAS EXCHANGE ENGINE

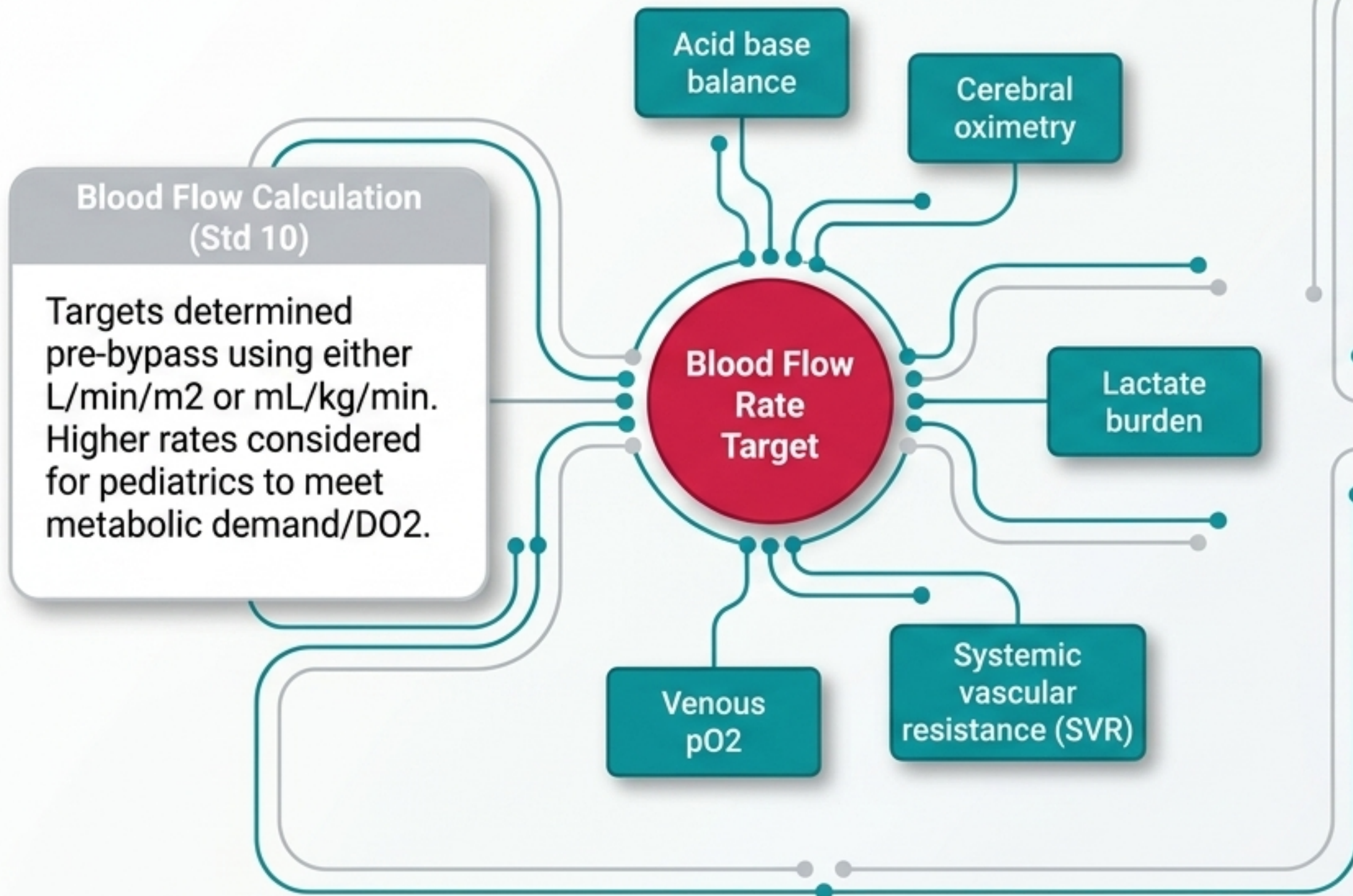
[TAG: PHYSIOLOGY]

Gas Exchange Protocol (Std 9): Must account for patient risk profile, oxygenator design, blood flow, temp, metabolic demand, and cerebral oximetry. Point-of-care testing utilized for accurate analysis.



PILLAR 4 | HEMODYNAMICS: FLOW & PRESSURE DYNAMICS

[TAG: PHYSIOLOGY]



Blood Pressure Targets (Std 11)

- Treatment algorithm defined prior to bypass.
- Acceptable ranges established based on age/weight.
- Variances must be documented and communicated to the physician-in-charge to adapt the management plan.

The Prime Challenge (Std 13): Prime composition critically impacts the small circulating blood volume of pediatric patients.

Destabilizing Impacts to Weigh

- Electrolyte levels
- Colloid osmotic pressure
- Coagulation
- Dilutional hematocrit
- Osmolarity

Mandatory Interventions (When priming with exogenous blood products)

1. Obtain/document prime gas and electrolyte levels prior to initiation.
2. Adjust to correct physiologic abnormalities.
3. Shall use Prebypass Ultrafiltration (PBUF) and/or washed red blood cells during the prime.

Core Mandate (Std 15): Calculate predicted post-dilutional hematocrit prior to bypass. Maintain minimum acceptable hematocrit per protocol.

CIRCUIT OPTIMIZATION

- Miniaturize circuit size to reduce prime volume.
- Biocompatible coating on all surfaces.
- Autologous priming (retrograde arterial/venous antegrade).

TRANSFUSION & SALVAGE

- Wash packed RBCs via autotransfusion or blood bank prior to transfusion.
- Perioperative cell recovery.
- End-of-procedure circuit blood salvage.

PATIENT MANAGEMENT

- Point-of-Care hemostasis monitoring (Viscoelastic, Fibrinogen, Platelet mapping).
- Preoperative Acute Normovolemic Hemodilution (ANH).
- Reduce donor exposures by using same donor when possible. Consider age of transfused blood.

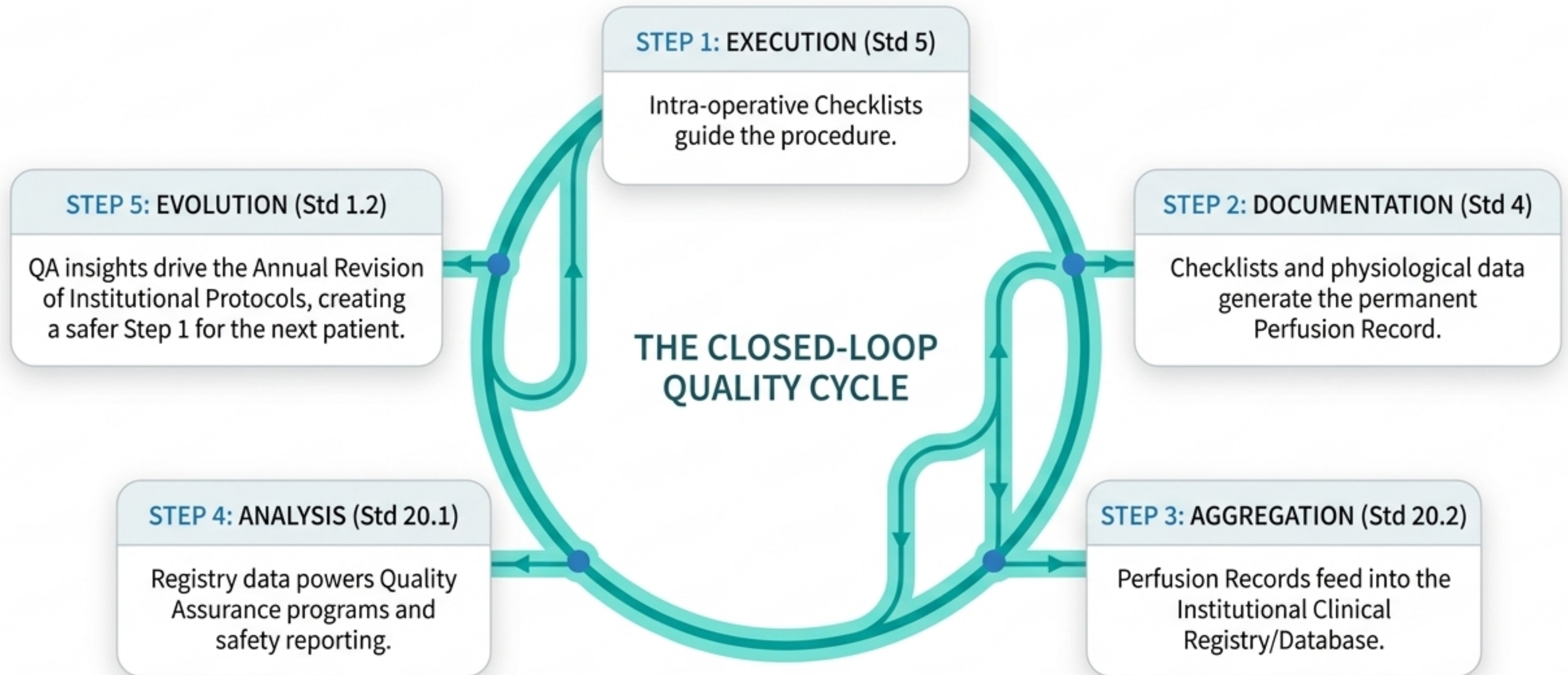
ANTICOAGULATION (Std 8)

- Define target ranges for ACT.
- Calculate initial Heparin dose via: Weight, Dose Response Curve, Blood Volume, or BSA.
- Must have process for managing Heparin Resistance.
- Heparin reversal (Protamine) must limit over-exposure and be confirmed by ACT/titration.
- Cardiotomy suction discontinued at onset of Protamine (Std 14).

FLUID MANAGEMENT (Std 16)

- Fluid balance continuously monitored and documented.
- Consider Modified Ultrafiltration (MUF) to optimize hemodynamics/hematocrit.
- Consider Dilutional or Zero Balance Ultrafiltration (ZBUF) during bypass.

SYNTHESIS: THE CLOSED-LOOP QUALITY ECOSYSTEM



The AmSECT Guidelines provide the scaffolding; the surgical team builds the culture of safety.