

# **Development and validation of a checklist for cardiopulmonary bypass**

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## **ABSTRACT**

**Introduction:** Risk prevention protocols related to patient care have been developed to reduce the incidence of adverse events in health care services. Cardiopulmonary bypass (CPB) can trigger several complications, including physiological problems, electrical, mechanical and human failures or defective components. In order to promote patient safety and the identification of failures before they can cause damages, it is necessary the use of a checklist for all surgeries. **Objective:** To prepare and validate a checklist for cardiopulmonary bypass. **Methodology:** A consensus validation methodology is applied in this study, in which the Delphi technique was structured for the instrument's development. Five perfusion experts, with at least five years of experience, had an active participation in this research. First, a questionnaire was structured, based on the comprehensive review of the relevant literature. Then, two rounds of assessments were conducted, allowing collection of experts' opinions. **Results:** In a first moment, a 42-item list was prepared and sent to the 5 experts for analysis. Based on participant's responses, certain elements were accepted, excluded, and suggested. After that, a second 37-item list was assessed by the experts, resulting in all 37 items that had an average assessment  $\geq 4$  and standard deviation  $\leq 1.0$  of acceptance. Based on these results, a 41-element checklist was developed, and these elements were considered crucial and relevant for the concerned analysis. **Conclusion:** The use of specific checklists for cardiopulmonary bypass comes into view as a highly proficient strategy, capable of promoting substantial improvements in the procedure safety and quality. The implementation and approval of this checklist should be considered.

**Keywords:** cardiopulmonary bypass; checklist; patient safety

## 1. INTRODUCTION

Risk prevention protocols related to patient care have been developed to reduce the incidence of adverse events in health care services. These measures aim at promoting patient safety and the identification of failures before they can cause damages. Therefore, to develop efficient prevention actions, it is important to know the more critical processes that, as a consequence, are more prone to occur. <sup>[1,2]</sup>

Cardiopulmonary bypass (CPB) can trigger several complications that are mainly related to the interaction between blood and non-endothelial circuit of oxygenators, tubes, and reservoirs. The CPB effects on the body can result in endothelial edema, respiratory complications, neurological disorders, kidney injury, post-surgery bleeding. <sup>[3,4]</sup> CPB presents not only physiological changes, but also carries risks if done incorrectly, whether due to mistakes during the circuit assembly or defective components. Failures can be electrical or mechanical, encompassing a wide range of events, such as cracks, disconnections, air embolism, hemolysis, blood or gas flow obstruction, heat exchanger leakage or malfunctioning, and air blender malfunctioning. <sup>[5,6]</sup>

According to the guidelines proposed by the *Sociedade Brasileira de Cirurgia Cardiovascular* (SBCCV, Brazilian Society for Cardiovascular Surgery) and *Sociedade Brasileira de Circulação Extracorpórea* (SBCEC, Brazilian Society for Extracorporeal Circulation), it is necessary for the clinical perfusionist to use a checklist for all surgeries. These lists must be used as a checking guide, where each completed step must be checked and confirmed. Preferably, the checklist should be filled out by two individuals, one of them being the main perfusionist. However, if a second professional is not available at the time of checking, it is crucial to adopt a systematic-oriented routine of the list items to minimize the occurrence of adverse events. <sup>[7,8]</sup> The American Society of Extracorporeal Technology (AmSECT), recommends that checklists shall be included as part of the patient's permanent medical record.<sup>[9]</sup>

The adequate preparation is essential to ensure patient safety during CPB, with patient safety considered inseparable from the quality of healthcare. European guidelines recommend the use of an institution-approved checklist before and during CPB, in the perioperative period (weaning from CPB, post-CPB, emergent reinstatement of CPB), and in procedures performed by clinical perfusionists. <sup>[10]</sup> AmSECT also recommends that the perfusionist should employ a checklist for additional perfusion services such as autotransfusion, intra-aortic balloon pump, and extracorporeal membrane oxygenation (ECMO). <sup>[9]</sup>

Human failure and poor maintenance of devices can contribute to the occurrence of accidents. The surgical team interaction, the early diagnosis, and the prompt intervention have shown to be crucial for a favorable outcome. Therefore, the clinical perfusionist plays a crucial role in cardiopulmonary bypass procedures, and their involvement is of utmost importance. <sup>[6]</sup> It is vital for the perfusionist to adhere strictly to established procedures to ensure patient safety throughout the entire duration of CPB. <sup>[11]</sup>

The assembly of the extracorporeal circuit and the inspection for potential failures in the perfusion equipment before its clinical use are important. The technological progress is evident, like incorporation of alarms and fail-safe devices, but care continues to be vital for conducting CPB. However, the perfusionist's attention to detail and adherence to pre-bypass checklists are still the foundation for a safe practice. Human error is the leading cause of accidents, even more than mechanical failure. CPB equipment test needs to be carried out to ensure roller pumps and heater/coolers are functioning well. As for the centrifugal pump console, it must be checked to observe potential electrical power failure; the most common method to do so is temporarily disconnecting the energy line from the console and checking if the backup battery alarm is fully operational. After the CPB circuit is assembled, the oxygenator and blood reservoir are placed in their proper support. The gas supply connection, the arterial flow pump tubes, and the roller lines should be safely connected; after that, the rollers must be properly calibrated. The two water lines of the heat exchanger are connected to the oxygenator, then water starts to flow to ensure there is no leakage. <sup>[11,12]</sup>

The checklist format is a process of continuous monitoring capable of developing efficient prevention actions, improving the cardiopulmonary bypass practice and providing a safer support to patients during a surgical procedure. The objective of the research was to develop and validate a checklist for cardiopulmonary bypass.

## 2. METHODOLOGY

A validation methodology based on expert consensus was applied in this study, using the Delphi technique to develop and evaluate the instrument. The Delphi method, a structured communication process, involves multiple rounds of questionnaires, allowing experts to revise their responses based on feedback until consensus is reached. In this study, two rounds were conducted to develop the checklist. The research was conducted from March to May 2023. The study was approved by the Research Ethics Committee of the Instituto Dante Pazzanese de Cardiologia (IDPC) – São Paulo, with the CAAE [Certificate of Presentation for Ethical Appreciation] number: 67490723.5.0000.5462.

Five clinical perfusionists with specialization recognized by the *Sociedade Brasileira de Circulação Extracorpórea* [Brazilian Society for Extracorporeal Circulation] and working in the area for at least 5 years have participated in the research. Each one of them was invited through an informative letter in which the study description and all stages were duly outlined. Also, the participants signed the Informed Consent Form (ICF) and were free to withdraw from the research at any moment.

An initial questionnaire was developed based on relevant contents selected according to the project's purpose. A detailed review of the literature was made, focused on the pre-bypass care and aiming at finding the information required for a safe perfusion. Based on these findings, essential safety actions were identified in the cardiopulmonary bypass practice, which became the items to be checked for the instrument in making. This preliminary list had 42 items and, based on them, the instrument was sent to the subjects, and it was requested that they would accept or exclude the list stages during the first interaction, by marking YES or NO in the appropriate field. Also, the experts were encouraged to, if they wished so, include new tasks to the list, combine existing items, or provide further comments. This stage was the first

Delphi questionnaire round, in which the responses were collected and analyzed, and the agreement and disagreement points identified for the elements in the preliminary list. The score over 90% of acceptance would be kept in the list.

Based on the experts responses on the first round, a second list containing 37 items was prepared and sent once again to the subjects. A 1 to 5 scale was used to assess the importance and relevance of each item (1 = totally disagree and 5 = totally agree). The subjects were invited to review and reassess the scores, based on the results and feedback obtained in the previous round. A report was prepared with the summary of the results obtained in the first round.

The experts could attribute the score and had the opportunity to provide additional comments or rationale to the assessment. These comments were important to refine the understanding of results and provide valuable insights for the decision-making process. The comments and suggestions were considered in the refinement phase of the checklist.

According to the responses given by experts in the second round, the items that were not consistent with the statistical criteria of mean  $\geq 4$  and SD  $\leq 1.0$  would be excluded from the checklist. The final version was based on these results.

### **3. RESULTS**

The first round revealed a high agreement level between the 5 specialists when it comes to most of the items assessed in the questionnaire. Out of the 42 elements on the list, 38 had an approval score over 90%, marked as “YES”, showing strong consensus points between the specialists in the preliminary questionnaire. However, it is important to point out that 4 items (CUSTODIOL SOLUTION; VOLTS - 110/ 220; LEVEL SENSOR; BUBBLE SENSOR) were scored under 90% or did not receive enough responses to determine a clear consensus. The percentage of approved items in a total of 42 was approximately 90.48% (38) and the percentage of non-approved items was approximately 9.52% (4). These results highlighted the need of a deeper analysis and additional discussions for the subsequent Delphi questionnaire rounds (Table 1).

Therefore, 2 items (CUSTODIOL SOLUTION; VOLTS - 110/ 220) were excluded for not complying with the 90% of acceptance condition and 4 (PATHOLOGY; EQUIPMENT CLEAN; MACHINE BATTERY; ICE) were included as a suggestion by the specialists. Ten elements was rewritten or repositioned (HEATER; COOLER; INITIAL TEST; ROLLERS; WATER LINES; HEAT EXCHANGER; DRIVER; PUMP BATTERY; BLENDER – FIO2, FLOWMETER), resulting in a more comprehensive data, and 2 (LEVEL SENSOR; BUBBLE SENSOR) items from the previous round under 90% of approval were kept in the second list, considering that, even though they are not included in the reality of the professionals, they may represent a highly potential perspective in the future. After the analysis of the second round results, all the 37 items reached a mean  $\geq 4$  and SD  $\leq 1.0$  (Table 2). Three items were additionally suggested for inclusion in the final checklist.

Based on the results obtained in the last round, a cardiopulmonary bypass checklist has been developed. This document covers all items and checks required, from identification of components to checking devices and operational tests. The items were divided into 10 topics and 3 elements were included in the last round after suggestion by the specialists: VENOUS / ARTERIAL TEMPERATURE SENSOR, PRESSURE GAUGE and CANNULAE) (Figure 1).

#### **4. DISCUSSION**

The list we have developed encapsulates all the pre-bypass moments, from preparing the equipment to the initial procedure, showing aspects such as functional device tests, identification of circuit components, preparation of equipment, and observing potential CPB-related failures. The purpose of the checklist is to ensure the proper execution of essential steps and necessary verifications for the efficient functioning of the system. The guidelines published by the Brazilian Society for Cardiovascular Surgery and Brazilian Society for Extracorporeal Circulation <sup>[8]</sup> as well as the perfusion checklist developed by American Society of Extracorporeal Technology <sup>[9]</sup> propose that the perfusionist use this checklist in all CPB procedures, and to include it in the patient's medical chart. SBCEC and SBCCV recommend the use of a checklist throughout the perioperative period, which would involve

not only the pre-bypass period but also the circulatory assistance period and post-bypass; but a document in which the perfusionist highlights all pieces of information related to this period has been already established and used, which is called the “perfusion sheet”. This article is specifically focused on preparing a checklist for the period prior to the extracorporeal procedure starts, and we consider that we have attained this goal.

Standardization is one of the main benefits of the CPB checklist in cardiovascular surgery. CPB involves a set of devices and interconnected stages, and detail is crucial for the system’s operation. The checklist provides a systematic and consistent guide, which aims at limiting the possibilities of errors that are often caused by not identifying issues earlier or even by negligence of the professionals. Nicoletti <sup>[11]</sup> points out important elements to develop a checklist, with 9 topics suggested being crucial: (1) Patient identification data, (2) equipment, (3) materials, (4) surgery planning, (5) circuit preparation, (6) prime, (7) anticoagulation, (8) macro monitoring and patient micro-hemodynamics (9) temperature. The items suggested by Nicoletti <sup>[11]</sup> contain elements focused on the period pre- and intra-surgical. AmSECT <sup>[12]</sup> recommends using the perfusion checklist developed by them with the topics: weaning/termination (VAVD off) and post bypass (announce bypass terminated), or a reasonable equivalent. Our study focuses on the pre-CPB phase and highlights ten essential topics designed to enhance patient safety through early detection of adverse events. By carefully checking each item on the checklist, we enable the prompt identification of any failures before the procedure begins. This proactive approach allows for swift and effective interventions, ensuring continuity in the process.

The technical complexity and interdependence of devices require a systemic approach, in which every step is consistently and precisely carried out. It is essential to integrate this practice into the professional's routine, making it a habit process. The standardization after checking all elements in the cardiopulmonary bypass technique may reduce the variability between professionals. It is crucial that future studies analyze the ease of use, execution time, and team engagement with the developed checklist.

While checklists are crucial for ensuring safety and consistency in clinical perfusion practice, excessively long or redundant checklists can lead to disengagement and errors from routine memorization. Drawing parallels to the aviation industry, where checklist fatigue has



been well-documented, we will suggest focusing on critical parameters directly related to patient safety and eliminating redundant steps. This selective approach ensures that the checklist remains an effective tool for error prevention without overwhelming the user.

A limitation of the study was the number of the participating judges. Five perfusionists were included in the research from the same center/service, however, it would be important to expand the criteria used to compose the sample of experts. The involvement of professionals from more than one health service and the participation of some professionals who work in the surgical environment, such as cardiac surgeons and anesthesiologists, would also be interesting.

## **5. CONCLUSION**

The use of specific cardiopulmonary bypass checklists comes into view as a highly proficient strategy, capable of promoting substantial improvements in the procedure safety and quality, being vital to ensure excellence in care for patients undergoing cardiovascular surgeries. The implementation and approval of this checklist should be considered as a practice recommended in cardiovascular surgery-aimed institutions and services, aiming at providing safer and successful results.

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**TABLE 1:** Preliminary list with 42 elements. The score over 90% of acceptance would be kept in the list.

Items Version 1		Validity of the item
<b>PATIENT</b>		
01	IDENTIFICATION / WEIGHT / HEIGHT	Valid
02	SURGICAL PROCEDURE	Valid
03	CALCULATIONS (Heparin / Flows)	Valid
04	BLOOD PRODUCTS CHECKING	Valid
<b>EQUIPMENT</b>		
05	POWER CABLES	Valid
06	COOLER	Rewritten/ Repositioned
07	HEATER	Rewritten/ Repositioned
08	VOLTS - 110/ 220	Excluded
<b>CPB MACHINE</b>		
09	INITIAL TEST	Rewritten/ Repositioned
10	HAND CRANK	Valid
11	LEVEL SENSOR	Valid, not supported exclusion
12	BUBBLE SENSOR	Valid, not supported exclusion
13	ROLLERS	Rewritten/ Repositioned
14	WATER LINES	Rewritten/ Repositioned
15	HEAT EXCHANGER	Rewritten/ Repositioned
<b>CENTRIFUGAL PUMP</b>		
16	CONSOLE	Valid
17	FLOW SENSOR	Valid
18	MANUAL HAND CRANK	Valid
19	OPERATIONAL TEST	Valid
20	DRIVER	Rewritten/ Repositioned
21	PUMP BATTERY	Rewritten/ Repositioned
<b>GAS SUPPLY</b>		
22	O2 /AIR REGULATION VALVE	Valid
23	LINES: O2 /AIR (Connected)	Valid
24	BLENDER - FIO2	Rewritten/ Repositioned
25	FLOWMETER	Rewritten/ Repositioned
<b>MATERIALS</b>		
26	PHARMACY KIT	Valid
27	OXYGENATOR AND COMPONENTS	Valid
28	REYNALD CLAMPS FOR TUBES	Valid
<b>CIRCUIT PREPARATION</b>		
29	SAFELY CONNECTING THE TUBES	Valid
30	PERFUSATE	Valid
31	CALIBRATION OF THE ARTERIAL ROLLER AND ASPIRATORS	Valid
32	AIR REMOVAL FROM THE SYSTEM	Valid
33	NO LEAKAGE IN THE CIRCUIT	Valid
<b>CARDIOPLEGIA</b>		
34	TEST IN THE CARDIOPLEGIA MODULE	Valid
35	CIRCUIT ASSEMBLY / CHECKING	Valid
36	CARDIOPLEGIA SOLUTION	Valid
37	CUSTODIOL SOLUTION	Excluded
<b>VACUUM SYSTEM</b>		
38	VACUUM REGULATOR	Valid
39	RELIEF VALVE	Valid

<b>BEFORE STARTING CPB</b>		
40	HEPARIN DOSAGE	Valid
41	ANTICOAGULATION / ACT	Valid
42	ARTERIAL LINE TEST	Valid

\*CPB – cardiopulmonary bypass; ACT – activated coagulation time

**TABLE 2:** Final list with 37 elements that were assessed as mean  $\geq 4$  and SD  $\leq 1.02$ 

<b>Items Version 2</b>		<b>Mean</b>	<b>SD</b>
<b>PATIENT</b>			
01	IDENTIFICATION / WEIGHT / HEIGHT	4.4	0.54
02	PATHOLOGY	4.4	0.54
03	SURGICAL PROCEDURE	4.4	0.89
04	CALCULATIONS (Heparin / Flows)	4.8	0.44
05	BLOOD PRODUCTS CHECKING	4.8	0.44
<b>EQUIPMENT</b>			
06	EQUIPMENT CLEAN	4.6	0.54
07	POWER CABLES	4.6	0.89
08	HEATER-COOLER	4.8	0.44
<b>CPB MACHINE</b>			
09	INITIAL TEST (Rollers / Water lines / Heat exchanger)	4.8	0.44
10	HAND CRANK	4.8	0.44
11	LEVEL SENSOR	4.0	0.63
12	BUBBLE SENSOR	4.2	0.44
13	BATTERY	4.6	0.89
<b>CENTRIFUGAL PUMP</b>			
14	CONSOLE / DRIVER / BATTERY	4.4	0.89
15	FLOW SENSOR	4.8	0.44
16	MANUAL HAND CRANK	4.8	0.44
17	OPERATIONAL TEST	4.4	0.54
<b>GAS SUPPLY</b>			
18	O2 /AIR REGULATION VALVE	4.6	0.54
19	LINES: O2 /AIR (Connected)	4.6	0.54
20	BLENDER / FLOWMETER / FIO2	4.6	0.54
<b>MATERIALS</b>			
21	PHARMACY KIT	4.6	0.54
22	OXYGENATOR AND COMPONENTS	4.4	0.89
23	REYNALD CLAMPS FOR TUBES	4.4	0.89
24	ICE	4.6	0.89
<b>CIRCUIT PREPARATION</b>			
25	SAFELY CONNECTING THE TUBES	4.8	0.44
26	PERFUSATE	5.0	0.0
27	CALIBRATION OF THE ARTERIAL ROLLER AND ASPIRATORS	4.4	0.54
28	AIR REMOVAL FROM THE SYSTEM	4.6	0.54
29	NO LEAKAGE IN THE CIRCUIT	4.4	0.54
<b>CARDIOPLEGIA</b>			
30	TEST IN THE CARDIOPLEGIA MODULE	4.2	0.83
31	CIRCUIT ASSEMBLY / CHECKING	4.4	0.54
32	CARDIOPLEGIA SOLUTION	4.2	0.97
<b>VACUUM SYSTEM</b>			
33	VACUUM REGULATOR	4.6	0.89
34	RELIEF VALVE	5.0	0.0
<b>BEFORE STARTING CPB</b>			
35	HEPARIN DOSAGE	4.4	0.54
36	ANTICOAGULATION / ACT	4.6	0.54
37	ARTERIAL LINE TEST	5.0	0.0

\*CPB – cardiopulmonary bypass; ACT – activated coagulation time

## CHECKLIST

PATIENT: \_\_\_\_\_

ID: \_\_\_\_\_

### Cardiopulmonary Bypass

- ADULT PATIENT       CHILDREN PATIENT

#### PATIENT

- IDENTIFICATION / WEIGHT / HEIGHT
- PATHOLOGY
- SURGICAL PROCEDURE
- CALCULATIONS (Heparin dose / Adequate Assistance Flows)
- AVAILABLE BLOOD RESERVE

#### EQUIPMENT

- EQUIPMENT CLEAN
- POWER CABLES INTEGRITY
- HEATER-COOLER OPERATION

#### CPB MACHINE

- INITIAL TEST (Rollers / Water lines / Heat exchanger)
- HANDCRANK AVAILABILITY
- LEVEL SENSOR
- BUBBLE SENSOR
- VENOUS/ARTERIAL TEMPERATURE SENSOR
- BATTERY LIFE

#### CENTRIFUGAL PUMP

- CONSOLE / DRIVER / BATTERY
- FLOW SENSOR
- ENERGY CABLES INTEGRITY
- MANUAL HANDCRANK AVAILABILITY
- OPERATIONAL TEST

#### GAS SUPPLY

- O<sub>2</sub>/AIR REGULATION VALVE
- LINES: O<sub>2</sub>/AIR (Connected)
- LENDER / FLOWMETER / FIO<sub>2</sub>

#### MATERIALS

- PHARMACY KIT
- OXYGENATOR AND COMPONENTS
- REYNALD CLAMPS FOR TUBES
- PRESSURE GAUGE
- CANNULAE
- ICE

#### CIRCUIT PREPARATION

- SAFELY CONNECTING THE TUBES
- PERFUSATE
- CALIBRATION OF THE ARTERIAL ROLLER AND ASPIRATORS
- AIR REMOVAL FROM THE SYSTEM
- NO LEAKAGE IN THE CIRCUIT

#### CARDIOPLEGIA

- TEST IN THE CARDIOPLEGIA MODULE
- CIRCUIT ASSEMBLY / CHECKING
- CARDIOPLEGIA SOLUTION

#### VACUUM SYSTEM

- VACUUM REGULATOR
- RELIEF VALVE

#### BEFORE STARTING CPB

- HEPARIN DOSAGE
- ANTICOAGULATION TEST / ACT
- ARTERIAL LINE TEST (Presence of resistance)

DATE: \_\_\_/\_\_\_/\_\_\_      PERFUSIONIST: \_\_\_\_\_

X Checked

⊖ Not Applicable

**Figure 1:** The final version of the cardiopulmonary bypass checklist with 10 topics and 41 carefully selected checking items.



