Consensus Statement on Electronic Medical Record Usage and Cardiopulmonary Bypass

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Abstract

Background: The adoption of electronic medical records (EMRs) for cardiopulmonary bypass (CPB) procedures has been slow within the perfusion community, despite the widespread use of electronic health records (EHR) in hospitals. This consensus statement aims to provide recommendations for the implementation and use of EMRs in CPB-related care. The goals include promoting EMR adoption, ensuring standardization across platforms, facilitating quality improvement initiatives, and encouraging participation in data registries.

Methods: Using a modified Delphi methodology, the consensus group identified 16 key elements for EMR use during CPB, categorized into selection/ acquisition/ installation, perioperative, and post-procedure stages.

***Results*:** There were 82 statements identified across the 16 EMR elements, with 80.4% (*n*=66) achieving an average consensus score of 7.0 and higher. Consensus was not achieved in 19.5% (*n*=16) of the element statements. Key recommendations include integration with digital outputs of bypass pumps, connectivity with patient monitors, adherence to security standards, and the ability to customize and adapt EMR systems to specific institutional needs.

Conclusion: The survey results underscore the significance of user-friendly perfusion data acquisition systems in minimizing cognitive load, highlighting their ease of use and ability to enhance workload efficiency. Essential elements include connectivity and interfacing, especially with equipment and physiological data integration, along with the necessity for dependable data storage and backup solutions. Further research is needed to investigate the potential advantages of integrating clinical decision support and pharmaceutical information integration. By addressing these elements, the consensus statement aims to improve the quality of perfusion practice and patient outcomes in CPB procedures.

Background

The electronic health record (EHR) is a crucial tool for improving the accuracy and efficiency of documentation, as well as the quality of patient care. An EHR is a digital version of a patient's medical history containing information such as diagnoses, medications, test results, treatment plans, progress notes, and vital signs. According to global health surveys by the World Health Organization (WHO), EHRs offer several benefits, including enhanced quality, accuracy, and timeliness of patient information, insights into healthcare costs and outcomes, and support for patient mobility by making information accessible to multiple providers (1). Additionally, EHR data analyses can identify areas of concern and improve health services delivery (1).

The Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009 included over $19 billion to help medical facilities implement the electronic transmission of health information (2). The HITECH Act required medical facilities to adopt and demonstrate meaningful use of EHRs by the year 2014 to maintain Medicare and Medicaid reimbursement. By 2014, over 75% of hospitals had adopted at least a basic system, and over 96% had a legal agreement to proceed with an EHR, by 2021 over 86% of non-Federal general acute care hospitals had adopted a 2015 edition certified EHR (2,3).

EHRs offer a complete overview of a patient's health and are intended to be shared among various healthcare providers. In contrast, electronic medical records (EMRs) are typically part of the patient's EHR and are primarily used within a single care unit for medical purposes. The first use of EMR-based computerized data acquisition during CPB was reported in the mid-1980s (4,5). However, despite the ubiquitous use of EMRs at hospitals in the United States, adoption has been slow in the perfusion community. It is estimated that approximately half of the clinical perfusionists in the U.S. are still charting on paper (6). As such, providing information and education to the community of perfusionists may encourage the successful and useful adoption of EMRs. The American Society of Extracorporeal Technology (AmSECT) Board of

Directors sought key opinion leaders to develop a Consensus Statement on the use of EMRs in CPB-related care. “Clinical consensus statements represent expert opinions developed by subject matter specialists and refined through an explicit methodology designed to identify areas of agreement and disagreement. Unlike clinical practice guidelines, which are based primarily on high-level evidence, clinical consensus statements are particularly relevant in situations where evidence is limited or absent, yet meaningful opportunities remain to reduce uncertainty and enhance the quality of care.” (7)

As outlined in the Clinical Consensus Statement Manual, developed by The American Academy of Otolaryngology-Head and Neck Surgery (7), the group consisted of highly engaged volunteers, many of whom were early adaptors of electronic medical records. The three writing committee chairs are all early adaptors and strong advocates of EMR utilization. Of the remaining volunteers, two were selected based on their expertise in consensus statements development, several are involved in quality improvement initiatives, have prior experience with consensus statement authorship and represent a diverse group of perfusionists recognized as advocates for perfusion EMR adoption.

The goals of this Consensus Statement related to EMRs for CPB-related care are to [1] suggest best practices and requirements of an EMR, [2] promote and facilitate adoption, [3] create consistency across platforms and users, [4] create tools for quality improvement initiatives that are enabled by the use of EMRs, and [5] to encourage participation in local and national perfusion data registries.

Methods

The EMR Consensus group utilized the Clinical Consensus Statement Manual developed by the American Academy of Otolaryngology (7). The manual suggests using a modified Delphi methodology to develop a consensus statement related to the adoption of EMRs for the perfusion community. A Delphi study is a widely used technique to obtain input from a group of experts in a structured manner. This methodology has been used by other medical specialties to guide the characteristics and use of EMRs, including dental care, cardiac surgical nursing, family medicine, and internal medicine (8-11). The Delphi method is a process of providing experts with multiple rounds of questionnaires. The EMR consensus committee used SurveyMonkey (San Mateo, CA, USA) and a nine-point Likert scale to achieve consensus. The consensus group used a cutoff score of 7 to determine agreement according to the Manual (7). The group completed the surveys anonymously on SurveyMonkey and the scores were calculated by the platform without the host seeing any individual responses. After each round, the responses were aggregated and shared with the group. The group met after each of the two rounds and debated the items that did not exceed 7 points on the Likert scale. Each element was open for debate at all times. There were two rounds of voting on each element of an EMR. The committee also determined the highest priority topics to be included in the statement. The experts adjusted their responses based on the group response, with the ultimate result being a combined consensus of the group. A statement was considered to reach a consensus when the final point score was greater than 7, and the statement was debated in cases where the score came close to 7. The consensus group determined sixteen different elements related to the use of an EMR during cardiopulmonary bypass (Table 1). The group then placed the elements in three separate categories, selection/acquisition/installation, perioperative, and post-procedure, to sort the stages of use of an EMR. (Table 2).

Results

There were 82 statements identified across the 16 EMR elements. Following the second round of voting, 66 statements received an average score of 7.0 or higher. Scores ranged from 7.0 to 8.88, meeting the criteria for group consensus. The group was unable to reach a consensus on 16 statements, with scores ranging from 5.47 to 6.88. The statements that were near agreement were vigorously debated to achieve agreement or disagreement (Supplementary Table 1).

Discussion

Some of the first electronic perfusion records were created by perfusionists who were computer enthusiasts. The earliest versions were so simple the perfusionist had to enter the data by hand on a keyboard, a huge distraction. Riley et al. developed one of the first automated data collection systems, and the results of his work were published in 1985 (4). Heart-lung machine manufacturers were some of the first distributors of commercially available electronic perfusion records. The early programs created by perfusion equipment manufacturers were plug-and-play programs the perfusionist could set up and operate in a matter of hours. These early programs created a computer-generated flat file record, which alleviated the need to manually transcribe data during the procedure (12). Today, a modern perfusion record requires significantly more installation time involving the hospital information service department and often the Chief Information Officer of the hospital. When it comes down to ease of use and connectivity, the consensus group agreed that a program should, at a minimum, integrate with the digital output of the bypass pump. Moreover, the program should connect to the physiological hemodynamic monitor and ancillary patient monitors and should link directly to the patient's medical record. Consensus indicated that vendors should create programs that utilize uniform coding language and medical verbiage for ease of using data for quality and reporting. After some additional debate, “Can Auto-Populate Registries” met consensus with a ranking of 8.16. Essentially, auto-

populate in this context would be a function where the data could be transferred either directly or indirectly to the registry with necessary transformations occurring on the way. Some of the qualities that did not meet consensus but ranked between six and seven on the Delphi scale were links to pharmaceutical information for drug calculation and drug interactions, and links to guidelines and protocols.

Customization and adaptability describe the EMR platform's ability to adapt to specific institutional needs. The use of an EMR should reduce the variability of the final record and reduce the cognitive load of the perfusionist (12). An ever-changing record, multiple layers of menus, and the location of information may lead to an increase in cognitive burden (13). The ability to make changes to the basic setup, collect and record data at a custom rate, and easily document personnel exchanges all met consensus on both Delphi surveys (Supplemental Table 1). Overall, the consensus group also agreed that the ability to make changes to the configuration should be restricted to system administrators and that individual team member customization was not supported by the group. The group also agreed that there is no need to have a completely customizable setup, as this could undermine the goal of creating a manufacturer-validated EMR (14).

With the increasing risk of cyberattacks on hospital information systems, a thorough review and plan for perfusion EMR security is paramount. Early engagement between perfusion and the hospital information technology department(s) will improve the success of implementing a perfusion EMR. Requirements for hospital information system security should be collected and distributed to all potential EMR vendors to eliminate systems that may not meet institutional requirements.

Regulations for information security are defined in the Health Insurance Portability and Accountability (HIPAA) Act of 1996 (15). HIPAA security standards are grouped by three primary safeguards: administrative safeguards, general security plans, and training regarding

EMR security (16). Physical safeguards include facility and workstation access control along with plans for information backup. Technical safeguards include elements of user authentication, integrity of data, and transmission security. A complete list of HIPAA security requirements is maintained by the Department of Health and Human Services (17).

Risk analysis is the first administrative step in selecting a perfusion EMR (18). Some elements that should be considered in evaluating perfusion EMR systems include:

- What are the operating systems and the risk from outside attacks?
- Where does the data reside (hospital-owned server, cloud, etc.)?
- What other data sources does the system need to access (hospital EMR, laboratory data, billing, financial systems, registries, and possibilities?
- What access does the vendor need to the hospital information system?
- How are updates to the perfusion EMR system handled?
- How does the system handle security updates? Can updates be pushed while the system is in use?
- What audit logs are available for security monitoring and incident investigation?

A key step in EMR security is how to implement physical safeguards to protect the information system and equipment. Plans for restoring data and maintenance of operations during down periods, including loss of power, are required. Other physical safeguards to consider are who has access to the EMR system and user authentication management. Access to EMR systems should be controlled to prevent unauthorized users from accessing protected health information (PHI). Consideration must be given to the type of devices that have access to the EMR. Workstations will require various levels of protection to ensure they are secure versus personal digital assistants (PDAs), which may be more easily displaced. Institutional policies on technical security should address all device types used with the system. Special consideration must be

given if the EMR requires the use of electronic media such as flash drives or portable data storage. Details should be described by the vendor on how that information is encrypted or protected and if any residual PHI resides on the device after use.

Four technical implementation access safeguards should be addressed when selecting a perfusion EMR.

1. How do you identify the user?
2. What is the emergency access procedure?
3. Is there an automatic logoff?
4. How is data encrypted?

The consensus group agreed on both points with a high agreement of over an 8.5 score (Supplemental Table 1) that any EMR must meet cyber/institutional security requirements and be HIPAA compliant (or compliant for country of use). Not only is the security of the physical perfusion EMR important, but integration with other data sources is a key benefit of an EMR. During an evaluation of EMR systems, one should understand how the data contained in the EMR may be used for other applications such as education and quality initiatives. It is important to evaluate the data that will be used and how it will interface with other programs. For example, is the perfusion EMR system compatible with other programs for quality reporting (registry databases), or will others need access to the data for purposes other than simply completing a record of the procedure? Evaluation of compatibility and security between applications should be completed in the initial consideration.

Any new EMR platform acquisition will need to pass through institutional approval and integration as previously described. Following approval, implementation of the EMR platform requires structured processes for installation, education, and training of staff and customer support. Across all fields, IT implementation failure rates are estimated between 12 and 40

percent, with some of the highest reported rates being in healthcare (13). A 2006 systematic review found that customized installation according to the team's workflow, proper training of staff, and a well-planned process for support during and post-implementation are all critical steps in a successful EMR implementation (13)

Based on expert opinion, the consensus group assigned a 7.89 (Supplemental Table 1) ranking to the importance of the vendor providing a specific roadmap for ease of installation. Installation requires cooperation and ongoing support of institutional IT departments. However, according to Box et al., installation duties should fall primarily on the vendor, as the local IT teams learn the system and continue supporting the remaining clinical areas (14).

All elements of installation should be considered, from hardware to workflow integration and staffing schedules. During installation, published literature supports the use of a trained "clinical champion" or superuser (13). This champion will serve as a super-user with more rigorous training and the ability to assist other clinical staff (14). Facilities that utilized a champion experienced a quicker and smoother implementation than those that did not.

Clinical perfusionists may be called upon to perform life-saving duties 24/7, 365 days per year, accordingly, the consensus group assigned a high ranking (8.22) to the importance of the vendor providing 24/7 product support and troubleshooting. Although a lower consensus was reached for institutional 24/7 IT support, it was considered to be an important adjunct for successful implementation and long-term success. The technical tools being implemented mustn't become a barrier for clinicians when a patient requires their undivided attention (Supplemental Table 1).

When considering the involvement of the local IT team, it is important to advocate for close communication between them and the clinical personnel. The proximity and familiarity of local colleagues allow them to work together to optimize and continually improve their systems. Once the local IT team has defined the ongoing needs of the clinical staff, they may involve the

vendor in the development and implementation of the desired improvements (19-21). Periodic software upgrades and hospital server upgrades will require collaboration between both vendor and institutional IT departments to ensure ongoing compliance with hospital security protocols as well.

Training of staff can vary significantly based on the institution and the specific role of the users and super-users. The consensus group reached a ranking of 7.11 on the topic of defining adequate training for inexperienced users. However, defining what is considered “adequate” for unpracticed users can be challenging, and a standardized workflow surrounding the training of personnel should be developed and determined by each institution. Training can be accomplished through any combination of the following methods: in-person hands-on, instructional videos and user guides, as well as remote real-time web-based instruction. Both local IT teams and vendor-provided staff should be available to provide initial user support. Feedback from trainees should be considered to determine their readiness for implementation. Teams may find it helpful to employ the strategy of an additional perfusionist and vendor-provided clinical support specialist shadowing the primary perfusionist during early implementation. This may help in the ease and speed of integration as well as increasing the skill level and confidence of the end user. Training may take several days to weeks and will vary based on the complexity of the platform chosen and the support provided.

Alternatively, some experts suggest using a “shadow record.” This record is an unofficial documentation of the clinical case in a mock patient chart. This shadow record is to be completed by a perfusionist who is not responsible for the clinical care of the patient. The primary perfusionist will conduct the clinical case and document originally while their colleague completes the shadow chart. This process may continue for several weeks, depending on the size of the team and their comfortability with the system. Teams utilizing this process found that the actual “go-live” of the charting system was seamless due to their experience with shadow charting (12, 22).

There are unlimited configurations of heart-lung machines. Some teams strive for simplicity and an open field of vision, while others surround themselves with ancillary equipment and rely on remote viewing. Some machines are relatively stationary, and others may travel daily to work rooms or catheterization labs. Due to these variable conditions, weight and size must be considered when selecting EMR equipment for any type of perfusion console.

The consensus group assigned a 7.94 (Supplemental Table 1) ranking to the importance of weight when selecting an EMR platform – well above the 7.0 rank required to achieve consensus. The group's primary focus was the importance of the ability to transfer or move/swap out components safely during EMR device failure, with a consensus level of 7.82. Size and ease of exchange of a device might not seem that important, however, after becoming accustomed to the use of electronic data collection, when faced with even temporarily returning to the paper alternative because it is too difficult to change out a failed device is unsatisfactory. Exchange capability for all devices on the heart-lung machine should be considered, and weight and complexity are important considerations. The primary perfusionist would ideally exchange a malfunctioning device without fear of shoulder, wrist, or hand injury. The Bureau of Labor and Statistics reported that in 2020, hospitals reported an injury rate of 7.7 injuries per hundred employees, whereas in the field of construction, injuries occurred at a rate of 2.9 injuries per 100 employees (23).

Compliance with vendor-specific weight and size limitations received a lower ranking by the group (6.29) but cannot be discounted. A clinical engineer may deem this paramount – your machine's instructions for use (IFU) include tested specifications for mast height and diameter and maximum permissible loads on masts, systems, racks, and holders. If your machine travels frequently, you may have a personal stake in managing its weight. A pump tipping over because of an overweight mast is a patient safety issue that should be avoided.

The experts on this panel were clear on two things concerning remote viewing and monitoring of live perfusion cases. One, that remote monitoring is an important, forward-thinking asset that

perfusionists should embrace, and two, remote viewing and monitoring of an extracorporeal support case should not be abused (Supplemental Table 1). Committee members with remote monitoring experience were limited; however, they were the most vocal about quelling the possibility of abusing remote monitoring, leading to abusive treatment of team members. An internet search for "remote viewing in medicine" returns over 252,000 hits. Fortunately, many of those papers speak to the efforts of establishing remote monitoring, and many also address the associated moral and ethical challenges.

Remote viewing and monitoring have several benefits. The ability for a team to track the progress of cases in real-time and receive alerts to critical conditions allows them to deploy resources efficiently at the appropriate time. AmSECT has established an N+1 staffing model for patient care during cardiopulmonary bypass (3, 24). The N+1 strategy dictates N equals the number of operating rooms in use at any given time at a single site. For example, if there are two CPB cases, then three perfusionists should be available. A remote viewing system providing alerts and indicators related to case timing, checklists, and progress may allow for more efficient use of the additional team members, giving them the ability to monitor multiple cases from a single location.

Institutions use many different staffing models when it comes to caring for patients supported with Extracorporeal Membrane Oxygenation (ECMO). In many of these situations, those monitoring the system may not continually be at the bedside. A remote monitoring system provides an additional layer of information access to critical personnel. Fung et al. reported the use of remote monitoring leading to critical interventions two different times during a single ECMO run, providing an immediate response from the perfusionist who noticed an issue from a remote location (25). Staffing strategies employing both ECMO specialists and perfusionists are aided by remote monitoring, as highlighted by Phelps et al. (20). Their institutions use remote access to keep the perfusion team engaged in the care of the ECMO patient being monitored at

the bedside by an ECMO specialist (26). The team should be informed and engaged during the development process regarding how the system is used, when and what is being monitored, and clear objectives for the use of the system. Protection of PHI must be in accordance with hospital guidelines and regulations.

The display monitor should have adequate resolution with a large enough font that is easy to read. Additionally, the user should have the ability to highlight the most essential information. One way to bring attention to the most essential information is by customizable compliance alerts that highlight relevant information or provide "pop-up" messages to bring attention to the most essential information. Compliance alerts based on customizable, preset clinical values or conditions may improve the reaction time and performance of perfusionists (26). The ideal EMR alerts the clinician to variations from optimal care paths (25, 27).

The organization of information should have a customizable and logical arrangement of data and events that is flexible enough to allow convenient displaying and documentation.
The information displayed should follow the natural order or progression of the case. The arrangement of data entry elements in a logical fashion is an important aspect of EMRs and may improve efficiency while minimizing errors. A consensus was found on all elements of the presentation of information (Supplemental Table 1). A study investigating the logical organization of medications in the EMR revealed that anesthesia providers documented medications more efficiently and accurately when medications were grouped by category (fluids, coagulation, antibiotics, etc.) versus when organized alphabetically (28). This study supports the idea that semantic matching may be better than alphanumeric and other methods for organizing information (29). It is also recommended that users be able to switch between numerical tables and graphical charts to visualize trends more easily when necessary. The electronic medical record should also incorporate the effective integration of best practices and guidelines. When

designed well, effective use of the EMR can improve adherence to best practices and clinical care guidelines (29-31).

Cognitive load, often referred to as mental load or mental effort, refers to the balance between one's cognitive resources and the demands imposed by a task. Excessive cognitive load is associated with compromised decision-making, which can affect patient safety and outcomes. Perfusionists managing CPB experience an elevated level of cognitive strain that is both complex and mentally demanding, and thus, a concerted effort should be employed to minimize additional cognitive load from an EMR to assist in error reduction. A consensus was reached on both Delphi surveys that the EMR should exert minimal distraction and be easy to use. Usability is an especially important aspect of an EMR, which will set the groundwork for perfusionists to carry out their tasks safely, effectively, and efficiently. Helpful functions that allow for a reduction in interactions could include preset clinical profiles and preset dropdown lists/comments. Additionally, the consensus group highly favored the ability of the EMR to support automatic calculations, with scores of 8.44 and 8.65 in each round of voting. Checklist integration with any perfusion record is an essential tool used by the perfusionist to operate the heart-lung machine safely and reliably. The ability to integrate checklists into an EMR adds an invaluable layer of patient safety and documentation to the patient's permanent record. The group assigned a ranking of 7.89 (Supplemental Table 1) to checklist incorporation into the patient's permanent record. This should be no surprise as this has been an established standard by AmSECT and should remain a part of the patient's permanent medical record (2, 23). The group assigned the same ranking (7.89) to timestamp checklist completion within the electronic perfusion record. The ability to timestamp checklist completion within an EMR allows for better checklist adherence due to an increased level of accountability and more accurate perfusion record audits and could be a tool utilized for remote-viewing capabilities to gauge the progress of an ongoing case.

The group did not reach a consensus (5.71) on the matter of a checklist(s) being required for starting the “CPB On Timer.” This may indicate a concern regarding some resistance to “blindly” checking boxes to start the “CPB On Timer” in an emergent situation requiring a crash on cardiopulmonary bypass. Requiring a checklist as a gatekeeper to start a bypass timer has the potential to lead to essential checklist items being overlooked. Also, the group did not reach a consensus, assigning a ranking of 6.89 as to whether a checklist should be required for clinician exchange.

A record of each procedure performed by the perfusionist should be included as part of the patient’s medical record. The AmSECT Standards and Guidelines for perfusion practice describe in detail the recommended components of the record (3, 24). The perfusion record should contain, at a minimum, pertinent patient demographics and risk factors, the procedure performed, personnel, and all perfusion equipment and disposables used in the procedure. Patient and device parameters, as well as laboratory results, should be documented at a routine frequency. The perfusion record should include free text comments from the perfusionist to document verbal orders as well as variances or deviations from protocol or expected procedural course.

The least sophisticated method of recording the perfusion procedure is the use of a printable document in which parameters are recorded by hand and, after completion of the case, scanned and uploaded into the EHR to satisfy the EHR Mandate of the American Recovery and Reinvestment Act (est. 2014) (4, 21,32). A second method of recording perfusion data is to transfer a record as a printable document format (PDF) from a perfusion interface system into the EHR (19). This method is used when perfusion technology is not fully integrated into the hospital’s EHR system.

Full integration and automation of the perfusion record could enhance perfusionist workflows as well as safety, allowing more time to focus on patient management. The consensus group

agreed on elements of the perfusion record (Table 2). The most advanced perfusion record to EHR interfaces directly and automatically captures the necessary parameters from multiple sources (4,16,19-21,33-37).

Commercially available electronic medical records must adhere to the HIPAA technical requirements for storage and backup. Technical specifications of data storage may be underappreciated and difficult to understand for clinical practitioners, but proper backup.

It is essential in protecting sensitive health information (16). Many of the requirements established in the U.S. 2003 HIPAA Security Final Rule 41, pertain to institutional EHRs and are due in part to the sharing and exchange of PHI across health outlets and organizations (37-39). Similar to HIPAA, the General Data Protection Regulation (GDPR) in the European Union (EU) imposes stricter requirements. “The GDPR protects any resident or citizen of the EU and includes names, email addresses, cookie data, location information, and data held by a hospital or doctor, which could be a symbol that uniquely identifies a person.” (40) Although the consensus group includes one member from the United Kingdom, one from the EU, and one from Australia, the statement is intended to provide guidance for perfusionists worldwide with the caveat that individuals should adhere to the regulations applicable in their respective countries.

While the information collected from EMR-based systems may be limited to a single provider or group, it still contains electronic information (e.g., name, date of birth, medical record number, and demographics) that is protected by law.

Therefore, most of the HIPAA security compliance and storage requirements apply to EMR systems. As such, it is paramount to include key stakeholders from the institution’s IT department in selecting and implementing perfusion data acquisition/EMR systems. Collaboration between hospital IT and device manufacturers should ensure both local and federal regulations are satisfied.

Adherence to these standards is enforced by the Office of Civil Rights (OCR) (39). The requirements established in the 2003 HIPAA Security Final Rule identify several areas of data storage: an up-to-date data backup and storage process, data storage redundancy and emergency access plan, and a disaster recovery and emergency access plan. Options for data storage generally include either on-site or cloud-based solutions. While off-site backup systems may confer protection from natural and physical disasters to local infrastructure, limits in internet bandwidth and availability may impact data transmission and retrieval to cloud-based systems. Institutions must weigh the risks and benefits of each, as well as evaluate the potential threats from physical disasters and cyberattacks. Other considerations for backup plans should include a power protection system/battery option to avoid downtime during power interruptions. Routine interrogation of the data recovery process is recommended to ensure proper redundancy systems are active. The HIPAA Security Rule also mandates those systems “create” a retrievable and exact copy of electronically protected health information, when needed, before the movement of equipment (41).

Regulations for the retention of patient records mandate data storage integrity and formatting for migration. Local and federal laws may require long-term storage of records that exceed the current storage architecture. Migration to a new digital storage system must be verifiable. Similarly, the removal of data that has exceeded the retention period must guarantee secure deletion from the system. To meet the technical standards set by the U.S. Department of Defense, a minimum of 256-bit encryption is required for data backup. Data must be stored for at least six years and be always restorable.

Other considerations for data backup solutions should include (38):

- Data Redundancy – Data should be securely stored in at least two disparate locations.

- Data Encryption – Any data stored in a digital format and hosted on HIPAA-compliant infrastructure must be encrypted with a 256-bit encryption standard and a two-factor authentication mechanism.
- Data Transfers – Any data that is transmitted over public networks and internet connections, such as using a virtual private network (VPN), must be encrypted with 256-bit encryption standard two-factor authentication.

The service provider must be capable of restoring backup data to its original or a new location. This process of continuous data protection must be audited and regularly tested.

The ability to assess the quality of perfusion conduct, separate from the rest of the surgical intervention, has long been discussed and is vitally important to the success and subsequent recovery of patients undergoing open-heart surgery. For many years, gross parameters such as rewarming rate, maximum temperature, lowest hematocrit, and minimum and maximum blood glucose levels were used to assess perfusion quality, as these were easily calculated from handwritten charts at low-frequency charting intervals (42). However, this information could only be calculated post-surgery and gave no provision for practitioner intervention at the point of delivery. Modern heart-lung machine (HLM) data management software systems receive inputs on a greater number of variables at a higher frequency and can output that data into both tabular and graphical formats, providing both absolute values and trends. This has become particularly relevant as more recent evidence demonstrates the importance of the "time below" threshold or area under the curve (AUC) in perfusion-related morbidity (43, 44, 45).

The expert group determined that there were two key factors relating to quality for any EMR system: firstly, it had to automatically create easily customizable individual and team quality reports (ranking 8.11, Supplemental Table 1) and secondly, that the data reported was reliable (ranking 8.44). Customizability is key for future-proofing any EMR system to the latest research on quality markers, as well as allowing the flexibility to tailor to individual patient

cohorts (for example, pediatrics versus adults). Providing both individual and departmental-level quality reports enables the identification of both good and poor practices, which can then be used for benchmarking against other institutions.

The AmSECT EMR consensus group loosely followed the Clinical Consensus Statement Development Manual published by the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) (7). The EMR group could not find enough evidence-based research to create a clinical practice guideline but found ample observational studies and expert-level consensus to create a consensus statement. The clinical consensus statement should provide areas for improvement in the quality of care for patients and provide a roadmap for future peer-reviewed research. The AAO-HNSF manual suggested using the Modified Delphi Technique, which the EMR group adopted as a method to determine which elements of an EMR reached consensus. The AAO-HNSF paper suggested a group of 8-10 or more members for a consensus group. The EMR group consisted of sixteen perfusionists and one non-perfusion expert. The AAO-HNSF paper also mentioned only recommended taking 6-8 months to finish the paper; the perfusion group took almost two years from start to finalizing the paper. The AAO-HNSF suggested that all members of the group needed to attend all calls.

The majority of perfusionists attended the conference calls, and as most of us are used to communicating via email and video conferencing platforms, we did not hold members to task on the calls. The Chair and assistant chairs completed the primary literature search and assigned the seventeen members in two-person teams to read each of 7 different papers related to EMR use that were determined to be useful in the clinical perfusion setting.

The group then divided each of the 16 elements into sub-elements and categorized them across three domains of perioperative surgical care: (1) Selection, Acquisition, and Installation; (2) Intraoperative; and (3) Post-Procedure. Since some elements applied to more than one domain - for example, “Supply and Equipment Traceability” spanned all three domains - the process

resulted in a total of 82 consensus statements. These statements were developed during group Zoom calls, where the wording was refined and agreed upon through iterative discussion.
Of these 82 consensus statements, only 10 failed to reach consensus, and six achieved near consensus. Notably, the elements that did not reach consensus were generally considered unnecessary or not sufficiently important to the perfusion community at this time. The group held conference calls after each round, during which there was spirited debate between those in consensus and those opposed.

The cognitive load elements achieved consensus on all but two items. Clinical decision support reached near consensus with scores of 6.78 and 6.88. Potential hyperlinks for procedures and guidelines reached consensus with the first vote, 7.11, and only near consensus, 6.65 on the second vote. Under the Connectivity/Interfacing/Flexibility element, “Can auto-populate registries” did not reach consensus with votes of 6.11 and 6.25. “Links to pharmaceutical information for drug calculations and drug interaction” only reached a consensus level of six. The group may have considered links and hyperlinks a source of distraction and an increase in cognitive load. Communication from the EMR to other devices via Bluetooth only achieved a level of 5.89 on the first survey and 5.94 on the second survey. Bluetooth was the least reliable method to connect devices.

For the Customization element, “Can make changes or make a completely customizable set-up" had no consensus on the first vote and only near consensus on the second vote primarily because the group agreed that a manufacturer-validated EMR is important for reducing cognitive load in achieving best practices.

Interestingly, for the Installation/Train/Support element, the group first had a consensus rating on “Define what is adequate training for new users” of 7.11, but on the second vote, the element only achieved a vote of 5.94. The group agreed that each individual and team could make their own definition of what adequate training is. The only element that achieved consensus in Billing

was an added element, “Traceability of disposables and hardware,” which achieved an elevated level of consensus at 7.88.

The Weight and Size Element did not reach a consensus on “Complies with vendor-specific weight and size limitations" because a Clinical Engineer may deem this paramount – your machine’s IFUs include tested specifications for mast height and diameter and maximum permissible loads on masts, systems, racks, and holders.

Under Checklist Integration, “Required for CPB on Timer” did not reach consensus on the first round of voting but was voted to near consensus on the second round (6.53). It was thought that some might blindly click through the checklist to start bypassing in an emergency.

Overall, the EMR consensus agreed that most elements chosen by the group should be required of an EMR for use during CPB. It was also agreed that programs should strive to launch an electronic record soon. Although launching an EMR may seem daunting and expensive, if you break down the cost by the percentage of a medical institution's overall IT budget, the expense is exceedingly small. If you look at the cost per case, the investment could seem very reasonable. Although there is a perception that using an EMR can leave the team in a more vulnerable position, it may leave a team with a much clearer record of what took place during CPB. This may help a team interpret incidents post-bypass and protect perfusionists if incidents happen during bypass. Having data available for individual and team quality reporting will help identify good and poor perfusion practices.

Several limitations were noted in this consensus approach. Firstly, a consensus paper does not carry the same weight as clinical practice guidelines. While the consensus group recognizes the distinction between evidence and consensus, our peer-reviewed literature revealed a lack of published scientific evidence. The group also understands that 17 experts might be a small fraction of perfusionists in practice around the world. However, it is important to highlight that the group comprised perfusionists from various regions across the United States and

internationally, including the United Kingdom, Australia, and Belgium. Collectively, they had amassed thousands of hours of experience with different EMR systems utilized in adult and pediatric congenital open-heart surgery.

Conclusion

The survey results underscore the significance of user-friendly perfusion data acquisition systems in minimizing cognitive load, highlighting their ease of use and ability to enhance workload efficiency. Essential elements include connectivity and interfacing, especially with equipment and physiological data integration, along with the necessity for dependable data storage and backup solutions. Further research is needed to investigate the potential advantages of integrating clinical decision support and pharmaceutical information integration. By addressing these elements, this consensus statement aims to improve the quality of perfusion practice and patient outcomes in CPB procedures.

Conflict of interest

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Data availability

All available data are incorporated into the article.

Author contributions

RAD, LP, DF designed and conceptualized the research; RAD, DF performed the research and analyzed the data; all authors contributed to writing and editing the text, with GJ, AW, RA, DF, LP writing and completing the final edits; all authors contributed to the final version and accepted the final version

Ethics approval

No ethical approvals were required for this research

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Figures and Tables

Table 1

Minimize Cognitive Load
Connectivity/Interfacing/Flexibility
Communication
Presentation of Information
Adaptability
Customization
Installation/Training/Support
Perfusion Record
Data Storage/Backup
Reporting
Quality
Remote Viewing or Monitoring
Billing and Inventory now "Supply and Equipment Traceability"
Weight and Size of EMR Device
Security
Checklist Integration

EMR = Electronic Medical Record

Table 2

Selection / Acquisition / Installation	**Perioperative**	**Post Procedure**
What is important in selecting, purchasing and installing an EMR in your institution	What is important when using the EMR during a procedure?	What is important in using the Electronic Medical Record post-procedure?
System acquisition and installation	Connectivity/Ease of use	Connectivity/Ease of use
Connectivity/Ease of use	Remote viewing	Supply & Equipment Traceability
Customization/Adaptability	Cognitive Load/ Presentation of information	Quality
Security	Minimize Cognitive Load	Reporting
Supply & Equipment Traceability	Communication	Security
Installation/training/support	Adaptability	Checklist Integration
Weight and Size	Customization	
	Checklist Integration	
	Perfusion Record	
	Data Storage/Backup	
	Reporting	
	Quality	
	Supply & Equipment Traceability	

EMR = Electronic Medical Record

Figures and Tables

Table 1: Sixteen different elements related to the use of an EMR during cardiopulmonary bypass determined by the consensus group.

Table 2: Elements across the domains of perioperative surgical care

Supplemental Table 1: Delphi survey results of the EMR elements

Section 1	Cognitive Load Elements	Survey 1	Survey 2
A	Ease of use, does not distract	8.44	8.65
B	Improves workload	8.11	8.53
C	Creates legible record	8	8.29
D	Efficient: minimizes number of steps for interaction	7.78	8.53
E	Does not require memorization after initial training	6.11	7.71
F	Clinical Decision Support	6.78	6.88
G	Automatic calculation support	7.35	7.71
H	Drugs	7.47	7.59
I	Flows	8.44	8.47
J	Use of standardized clinical profiles	7	7.12
K	Use of Standardized drop-down lists for comments,	7.56	7.59
L	Ability for touch screens to minimize keystrokes.	6.78	7.82
M	Potential for hyperlinks for procedures and guidelines	7.11	6.65
N	Preset buttons for emergent bypass.	6.67	
Section 2	**Connectivity/Interfacing/Flexibility Elements**	**Survey 1**	**Survey 2**
A	To pump	9	8.88
B	To anesthesia monitor.	8.22	8.63
C	To all or most of patient monitors	8.11	7.88
D	Linked to patient chart	7.89	7.5
E	Uploads lab values automatically	7.67	7.75
F	Can auto-populate registries	6.11	6.25
G	Links to guidelines and protocols	6.67	7
H	Links to Pharmaceutical Information for drug calculations and drug interactions	6	6
I	Utilizes uniform language/coding verbiage	7.67	8.13
J	Frequency of data acquisition of specific devices	7	7.63
K	Whenever possible data acquisition should be validated and automated.	7.56	7.5
Section 3	**Communication Elements**	**Survey 1**	**Survey 2**
A	Direct via LAN to USB	7.44	7.47

B	WIFI	6.78	7
C	Bluetooth	5.89	5.94
D	RS-232	6.29	7
E	Cellular	x	x
Section 4	**Presentation Elements**	**Survey 1**	**Survey 2**
A	The information is in the natural order of the case	7.67	8.06
B	Effective use of language, relies on best practice and guideline language	7.56	8.06
C	Display has good resolution	7.89	8.06
D	Large enough font to see.	8	8.18
E	Effective information presentation.	8	8.06
F	Workflow is customizable	7.56	7.71
G	Alarm/Alerts notifications are customizable	7.33	7.59
H	Ability to highlight important information	7.11	7.71
I	Ability to switch between numerical and graphic data	7.44	7.12
Section 5	**Adaptability Elements**	**Survey 1**	**Survey 2**
A	Usable on multiple ECLS pump platforms	7.78	
Section 6	**Customization Elements**	**Survey 1**	**Survey 2**
A	Collects and charts data at rate set by user	7.11	7.12
B	Can make changes to basic set up	7.33	7.82
C	Can make changes completely customizable set up	6.33	6.88
D	Can make changes Ability to easily document a change in user	7.44	8.18
E	Can have individual usable customizable profiles	5	6
F	Can make changes protected by "admin" mode so important configuration is only changeable by certain users	8.56	8.29
Section 7	**Installation Elements**	**Survey 1**	**Survey 2**
A	Easily supported by Vendor for set up and maintenance	7.89	8.18
B	Vendor provides roadmap for installation, training and such	7.78	7.82
C	Vendor supported 24/7	8.22	7.71

D	Hospital IT supported for troubleshooting 24/7	7.11	7
E	Define what is adequate training for new users	7.11	5.94
F	Any EMR should go through institutional IT approval and integration	7.44	7.47
Section 8	**Patient Record Elements**	**Survey 1**	**Survey 2**
A	Ability to upload minimum standard data sets as defined by user or institution	8.11	7.94
B	Ability to upload patient data to auto-populate to the perfusion record Automatic upload to patient EHR Uploads as a PDF as a minimum	7.89	8.06
C	Automatic upload to patient EHR	7.89	8.18
D	Uploads as a PDF as a minimum	7.11	7.35
Section 9	**Data Backup and Storage Elements**	**Survey 1**	**Survey 2**
A	Storage on EMR device	6.67	7.94
B	Adequate safe and reliable institutional storage and backup of data	8.41	8.18
Section 10	**Reporting Elements**	**Survey 1**	**Survey 2**
A	Data Analytics	7.63	7.63
B	Ability to extract and format data in a useable way	8.44	7.88
C	Nonproprietary data analytic software language	7	7
D	User can set up data analytics	7.78	7.38
E	User can see data trends, make practice changes, and then track changes	8	7.25
Section 11	**Quality Elements**	**Survey 1**	**Survey 2**
A	Automatically creates easily customizable individual and team quality reports	8.11	7.25
B	Need for reliable quality data	8.44	7.5
Section 12	**Remote Viewing**	**Survey 1**	**Survey 2**
A	N+1 can watch multiple cases and provide help based on alerts.	6.89	7.24
B	Not to be used as punitive but rather used only for improving patient case	8	7.59

Section 13	**Billing Elements**	**Survey 1**	**Survey 2**
A	Ability to scan for inventory management	6.78	6.53
B	Ability to forecast disposable use	6	5.47
C	Equipment and inventory management capabilities	6.44	6.29
D	Billing capability	5.56	5.47
E	"New" Traceability of disposables and hardware.	x	7.88
Section 14	**Weight Elements**	**Survey 1**	**Survey 2**
A	Large enough to see but does not impede circuit visibility	7.78	7.94
B	Complies with vendor specific weight and size limitations	6.56	6.29
C	Ability to transfer or move/swap out components safely during EMR device failure	7.82	7.12
Section 15	**Security Elements**	**Survey 1**	**Survey 2**
A	HIPAA compliant (or compliant for country of use)	8.78	8.88
B	Meets Cyber/Institutional security requirement	8.78	8.75
Section 16	**Checklist Integration Element**	**Survey 1**	**Survey 2**
A	Incorporated in record	7.89	8.65
B	Timestamped	7.89	8.53
C	Required for “CPB On Timer”	5.71	6.53
D	Required for user change/SBAR	6.89	7.35
E	Includes lot numbers of Perfusion items for trace back	7.67	7.24

CPB = Cardiopulmonary Bypass, ECLS = ExtraCorporeal Life Support, EHR = Electronic Health Record, EMR = Electronic Medical Record, HIPAA = Health Insurance Portability and Accountability ACT, IT = Information Technology, LAN = Local Area Network, PDF = Printable Document Format, RS232=Recommended Standard 232, SBAR = Situation-Background-Assessment-Recommendation, USB=Universal Serial Bus

Acronyms/Abbreviations:

AmSECT = American Society of Extracorporeal Technology

PHI = Protected Health Information

HLM = Heart-Lung Machine

WHO = World Health Organisation

HITECH = Health Information Technology for Economic and Clinical HealthAct

PDA = Personal Digital Assistant

IFU = Instructions for Use

OCR = Office of Civil Rights

VPN = Virtual Private Network

AAO-HNSF = American Academy of Otolaryngology-Head and Neck Surgery Foundation

LAN = Local Area Network

USB = Universal Serial Bus

RS232 = Recommended Standard 232

ECLS = Extracorporeal Life Support

IT = Information Technology

EMR = Electronic Medical Record

EHR = Electronic Health Record

PDF = Printable Document Format

HIPAA = Health Insurance Portability and Accountability ACT

CPB = Cardiopulmonary Bypass

SBAR = Situation-Background-Assessment-Recommendation

ECMO = Extracorporeal Membrane Oxygenation

GDPR = General Data Protection Regulation

EU = European Union