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REVIEW ARTICLE

Point-of-Care Testing: General Aspects

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SUMMARY

Point-of-Care Testing (POCT) has been highlighted in the health care sector in recent decades. On the other hand, due to its low demand, POCT is at a disadvantage compared to conventional equipment, since its cost is inversely proportional to the volume of use. In addition, for the implementation of POCT to succeed, it is essential to rely on the work of a multidisciplinary team. The awareness of health professionals of the importance of each step is perhaps the critical success factor. The trend towards the continuous advancement of the use of POCT and the great potential of its contributions reinforce the need to implement quality management tools, including performance indicators, to ensure their results. This review presents some advantages and disadvantages concerning POCT and the real need to use it. A worldwide call for the availability of easy-to-use health technologies that are increasingly closer to the final user is one of the main reasons for this focus.
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INTRODUCTION

1.1 Point-of-Care Testing (POCT)

Point-of-Care Testing (POCT) is performed by laboratory equipment outside of the laboratory area; it is also known as bedside testing, rapid testing, and near-patient testing. These tests are performed near the patient and

provide a quick response; the sample is not transported, the analysis is simplified, and the operators do not have to be laboratory staff (e.g., patients, nurses, or doctors). The results of the rapid test may be used for screening, monitoring or diagnosis. POCT is used in hospitals, emergency rooms, specialized clinics, or ambulances, at home by patients performing self-monitoring, and in public health campaigns.

The shorter sample processing time stands out as a significant advantage over conventional methods; consequently, POCT enables faster medical decisions on treatments, reduces the length of hospital stays and, in some cases, reduces morbidity and mortality. In addition, the reduction of POCT analysis time results from the use of whole blood along with minimal sample transportation and preparation times [1].

To successfully implement POCT, one of the factors to bear in mind (Table 1) is the level of computerization in the testing location in order to ensure fulfillment of the questions below:

Which professionals will perform the POCT?
One can assume the involvement of nursing technicians, nurses, biomedical engineers, pharmaceutical-biochemical technologists, biologists, and physicians, since they have been previously trained.

How is it ensured that the controls will be carried out at the recommended frequency?
In cases where management is performed by software, one can configure the system so that it does not allow use of the equipment when the controls have not been passed in the appropriate form and frequency. In cases where management of the process is performed manually, it is advisable to make a major investment in operational training, since there will be no automatic locks. In these cases, it is suggested that the control data records be entered on spreadsheets or record dossiers to ensure traceability of the entire process.

How is it ensured that only qualified and previously trained people will perform the dosages?
Once again, if management software is used, this lock can be done through its system settings; otherwise, the system will rely on the awareness of those involved in the process.

How is it demonstrated that the annual retraining of users was carried out?
All training should be recorded so that these recordings can readily be consulted, if necessary.

What is the appropriate flow for issuing reports?
Reports may be issued automatically by the software that interfaces with the LIS (laboratory information system) or HIS (hospital information system), or they may be manually reported by qualified professionals.

Is the required traceability present at all stages?
It is necessary to carefully evaluate all of the steps involved in the process and highlight the existence of end-to-end traceability, ensuring the ability to recover quality control records until the report is released.

How is it ensured that the results released by the POCT are compatible with those released by the clinical laboratory?
It is advisable to make biannual comparisons in the cases where the same tests are performed at bedside and in the clinical laboratory. Using some samples (depending of type of material - ex: serum, plasm or whole blood), comparison with external or internal control.

Is there a proficiency test for each analyte measured by the POCT?
All POCT must have proficiency tests.

How will the generated waste be discarded?
In general, most of clinical laboratories have autoclaves so that their waste is treated before being discarded. However, in the case of POCT, it is difficult to reach an agreement on the best way of managing tubes and other materials that are used, and the way to discard waste is different from country to country [2]. In the remote areas, these materials will not be autoclaved, and transporting the residues to a laboratory, if it is distant, will not be permitted by law. This matter should be individually handled according to the needs and abilities of each institution.

Other questions that should be answered according to the institution's characteristics are whether the health insurance companies will pay for these tests, which cost center or operation unit of the health institution will bear the costs of these tests, and how the revenue or profitability will be divided.

The standard operational procedure should be as complete as possible and should include the following information:

- Sample type to be used
- Detailed collection procedure
- Material identification method
- Processing
- Methodology and possible interferences
- Reference values
- Instructions regarding quality control
- Layout of the results
- Frequency of calibrations and controls
- Method of recording possible events related to quality control
- Actions to be taken when the results are not normal, including critical values.

1.2 POCT Quality Indicators

Few studies specifically address the use of indicators in POCT. Lippi et al. [3] list the main aspects of POCT that are associated with each stage of the process:

- Pre-analytical aspects: medical request; identification and preparation of the patient; sample collection and manipulation; preparation of materials, equipment and the area
- Analytical aspects: quality control; calibrations; analytical performance; file of results
- Post-analytical aspects: reports; confirmatory tests; interpretation of the report and medical advice; patient follow-up; biological waste; revenues.

The Lippi study [3] also compared the analytical performance of a POCT system for glucose, cholesterol, and triglycerides when used by different professionals, one professional from a laboratory, and three others from pharmacies. The results demonstrated a greater analytical variation when the test was performed by professionals who are not familiar with the routines of clinical laboratories.

Studies of different centers have shown that pre-analytical factors are responsible for approximately 70% of the errors recorded in a clinical laboratory. Thus, in anticipation of the analytical process, a laboratory that intends to reach proper quality specifications should consider being aware of, controlling, and, if possible, eliminating some of the variables that may interfere with the results [4].

A study published in 2011 by O'Kane et al. [5] evaluated the POCT error rates for a series of tests that were performed over a 14-month period by applying a questionnaire related to quality. A total of 225 responses were obtained on more than 400,000 tests. The responses were mostly filed by clinicians, who reported considerably higher error rates than those observed in the centralized laboratories, and the reported errors predominantly occurred in the analytical phase. The errors were further classified into five grades according to the current or potential patient impact: absent, minimum, light, moderate, or severe. The results demonstrated that the observed impacts were largely absent or minimal, with minimal potential impact in most cases. However, approximately 20% of the cases had mild to severe potential damage to patients.

The need to implement a performance monitoring system for process quality, results, and patient impact is also recommended by other international organizations. For example, ISQua (International Society for Quality in Health Care) [6], in its guidelines for the development of Health Accreditation Standards, shows a special emphasis on the requirement that these standards should require the monitoring of aspects related to their efficiency and use of services, quality performance, clinical governance, and more.

Few studies have been published so far on specific performance indicators for these tests; however, the main performance dimensions to be monitored are comparable to those of the other laboratory tests that are processed in central laboratories. The performance dimensions must be aligned with specific points in the POCT, and they must consider each phase that is involved in the process.

1.3 POCT Accreditation - Standards and Guidelines

In 2006, an international standard was introduced (ISO 22870:2006) with specific requirements that are applicable to POCT. This standard is intended to be used in conjunction with ISO 15189, which describes the general requirements for competence and quality for medical laboratories [5], similar to a German standard [6]. The standards assume that the risks to the patient and to the facility can be managed by a well-designed, fully implemented quality management system that facilitates:

- Evaluation of new or alternative POCT instruments and systems
- Evaluation and approval of end-user proposals and protocols
- Purchase and installation of equipment
- Maintenance of consumable supplies and reagents
- Training, certification and recertification of POCT system operators
- Quality control and quality assurance.

Patient self-testing at home or in a community setting is not covered by these ISO standards.

In April 2016, the European Diagnostic Manufacturers Association (EDMA) published “Requirements for POCT systems - Proposal for an *in vitro* diagnostics (IVD) Regulation”, which argues that self-testing and point-of-care devices have fundamental differences and that it therefore makes sense to control them differently. The EDMA proposed that a technical review (determined by the class of the device) should be followed for point-of-care devices. In June 2016, a Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices was presented, but it has not been voted on yet [8].

In 2016, the Clinical Laboratory Standards Institute published “Essential Tools for Implementation and Management of a POCT Program”, which provides useful information for institutions that wish to perform POCT. It was written with the assumption that users will be people without expertise in laboratories. According to this standard: “Because of the enormous consequences stemming from unreliable test results, it is vital that results continue to be trustworthy and of high quality as these tests are transferred from the medical laboratory to the point of care. POCT is often performed by personnel not trained in medical laboratory practice and faces similar regulatory and quality management issues as laboratory-based testing. Once the decision to offer POCT is made, professionals in laboratory medicine should be involved in supporting and assessing the results of these services” [9].

In 2014, the US Center for Medicare and Medicaid Services (CMS) implemented new protocols for interpreting the legislation contained in the Clinical Laboratory Improvement Amendments (CLIA), which incorporate risk management principles and offer laboratories two options for quality control [10].

1) To use two levels of quality control/day, or
2) To develop an Individualized Quality Control Plan (IQCP) that reduces the frequency of use of a liquid quality control, but respects the manufacturer's guidelines, in order to obtain savings.

A two-year educational period is planned, and such protocols will take effect in 2017. Some authors, especially Westgard [11], are critical of this POCT quality control system, named "Equivalent Quality Control" or "EQC", and they have raised questions related to its ability to detect and prevent errors.

Lewandrowski [12], despite admitting that competency assessment is an important process to ensure quality testing in POCT, questions the current Joint Commission requirements; he suggests that the standards may be excessive for many POCTs. Neither the frequency of competency assessment nor the number of different methods required is based on any evidence of effectiveness, let alone cost-effectiveness. These requirements can be quite onerous and time consuming and, at the same time, they are largely arbitrary. Lewandrowski believes that the federal government and regulatory agencies should review the regulations related to POCT with an eye for streamlining the process, and that they should subject the specific regulations to an evidence-based cost-effectiveness analysis.

1.4 Operational controls related to POCT

In the process of selecting an analytical system, several general aspects, described below, should be considered to aid in decision making:

- Legal: required documents and records, health surveillance, international regulatory agencies, ministry of health, technical responsibility
- Economic: cost-effective price, payment period, payment terms, import expenses, installation expenses, coding, and procedures for billing the examination of users with supplementary health coverage or those in Brazil's Unified Health System (SUS)
- Operational simplicity
- Maintenance: spare parts, specialized technical assistance team
- Environmental: generation of waste and impacts to the environment
- Infrastructure: space, bank requirements, electricity (voltage, electrical current, frequency), water (type of reactive water required, volume of consumption), ambient temperature, humidity, luminosity, logic network, interfacing
- Supplier-linked: availability of reagents, adequate storage/logistics capacity, supplier reputation, reagent stability.

1.4.1 Verification and Validation

The validation process of new POCTs can be challenging due to the diversity of tests, existing instruments, and materials that can perform the measures and the distribution of the equipment. In addition, different types of samples (plasma, serum, capillary blood, saliva, urine, sweat or whole blood) can generate differences in results when measured on the same equipment; therefore, it is important to validate the analytical system with the specific samples that will be regularly used.

In some countries where POCTs are used in nursing homes, hospitals, outpatient clinics, medical offices or clinics, there are specific laws regarding the training and competence of the operators and their continuing education program [1]. In England, Northern Ireland, Wales, and Canada, operators must receive training to reach the desired level of competence, and only those operators who obtain certification can work with POCT. In Spain, training and evaluation programs are required for POCT operators in hospitals, medical offices, and clinics. In Germany, only training is required, but standard operating procedures are required at the place where the examinations are performed.

The validation process generates a validation report, operational procedures, a preventive maintenance plan for the equipment, supply planning, training and continuing education plans, internal and external quality control programs, a report design, a flow of communication for results and their recording in medical records, the establishment of a set of critical values and the actions to be triggered for these types of results, and the interfacing of the POCT with the laboratory information system and with the hospital management system (when the POCT is for intrahospital use) [1].

It is recommended to develop a catalogue of tests provided by the POCT, indicating the type of biological material to be manipulated, the name of the analyte and specialty within the laboratory, along with a description of the technology used, and the manufacturer. An example is described in Table 2.

1.4.2 Control Materials

The internal control materials (Continuous Quality Improvement - CQI) mimic the patient samples for an application and are used to test the results and their interpretations. They are liquid materials or are made of materials that are similar to the samples. They may be at normal or pathological (low or high) concentrations or may serve as positive or negative controls. They may be part of the kit or purchased separately. Their frequency of application will depend on several factors, including the impact of the reagents on the test, the stability of the reagents, the experience of the technical team, and regulatory requirements [13].

The records obtained from control materials indicate whether the operator has performed the procedures correctly. They include the data and time of CQI application, the lot number and date of control material, the acceptance interval of each control band that was applied, the lot number and date of the reagents or kit, and information on who performed the test. The internal quality control procedures are validated through interpretation of the data using specific statistical tools.

The best systems for quality control in POCT are those with the highest degree of control mechanisms built into their manufacturing, which enable the verification and monitoring of the analytical stage and offer the most advanced level of connectivity.

1.4.3 Interlaboratory comparison programs: External Quality Assessment (EQA) in POCT/proficiency tests in POCT

The aims of the POCT interlaboratory comparison programs (EQA) are as follows: to evaluate the participants' performance, the methods used, and the post-sale surveillance of *in vitro* diagnostic products (e.g., the European community assesses the adequacy of the cutoff level, the specificity of reactions in certain lots, and the interference in equipment due to corrosion and poor performance); to provide training to those involved; to assist in identifying operational problems; to promote the continuous improvement of performance; to compare results between laboratories; to standardize methods (by promoting the use of better calibration materials); and to contribute, as a service, licensing factors or even a refund by payment authorities.

Some difficulties in specific EQA for POCT arise due to program coverage, control materials (homogeneity, commutability, stability, safety standards and compliance), the adequacy of statistical procedures (number of results to be evaluated, significance level, data classification, use of parametric or non-parametric tests, whether consensus results will be obtained based on all results or related to the methods) and the diversity of methodologies that are currently available in the world market.

The choice of the provider of the proficiency tests must follow well-defined criteria, such as suitability of the supplier, scope of their offered programs, technical staff of the supplier, logistics, prices, frequency of application of each program, number and volume of control material samples for each round, and delivery times of the evaluation reports.

The application of EQA in POCT should follow some precautions related to the following issues: frequency of application; inspection of the control material immediately upon receipt; criteria for distribution of the control material; blind distribution of control material to those involved; care to apply these materials routinely, as if they were a regular measurement made in the POCT; proper recording of the results obtained and delivery to the proficiency test provider; and storage of the raw data that are generated.

When there is no external quality assessment mechanism with the official provider, alternative mechanisms may be introduced, as recommended by CLSI [14].

When receiving the results of an evaluation, there should be a system of disclosure, criteria for interpretation/analysis of performance, a definition of records for critical analysis, and an action plan for handling the results acquired if they are adequate, inadequate or do not have sufficient numbers for statistical analysis.

The Australian Government's Department of Health [15] requires participation in proficiency testing for peer comparison and review.

For the Ontario Ministry of Health [16], teams of hospitals and long-term health care institutions require compliance with the manufacturer's quality control specifications, which are monitored and analyzed by competent professionals and include non-conformance plans. However, in the Canadian province of Quebec and in New Zealand, the law requires the application of EQA in compliance with the requirements of ISO 22870. Germany, Spain and Ireland recommend a participation agreement with their national proficiency testing providers. Brazil requires, in accordance with ANVISA RDC 302 (Brazil National Health Surveillance Agency), an external quality assessment by official or alternative providers.

In the absence of a formal EQA program provided by official providers, it is recommended to develop alternative approaches that generate objective evidence to determine the acceptability of the test results.

1.4.4 Internal audits as an instrument for improving operational control

The internal audits are performed by experienced laboratory personnel who are prepared for the task of evaluating the quality system, the outlined processes, and the products. They should examine each laboratory process at regular intervals to observe its compliance to policies, legislation, operational efficiency, and the traditional aspects of control and safeguarding within the company. The auditor performs the following steps for quality control assessment:

- Evaluates the internal control system of the laboratory and defines its scope of action
- Verifies whether the addressed system is being followed in practice
- Evaluates the possibility of the system immediately revealing errors and irregularities
- Determines the type, date, and volume of the procedures to be audited
- Under this approach, the internal auditor evaluates the operations according to the scope of their defined objectives

The management team of the laboratory is responsible for the establishment of operational control, for the monitoring and verification of employees' actions, and for possible modifications to adapt the operational control to the new circumstances.

The responsibilities of the audit team are as follows:

- Observe the level of qualification of the team members in an audited laboratory to correctly exert the program of quality control in POCT
- Identify the level of compliance of the technical team to the POCT quality control program
- Investigate whether all control procedures are being performed
- Detect errors and irregularities
- Determine responsibilities for possible omissions in

Table 1. The various working groups in health services that are involved in POCT implementation and their activities during and after implementation.

Group involved	Activity during implementation	Activity post-implementation
Clinical Laboratory	Choose the type of POCT; Check the equipment registration; Validate; Describe the procedure; Indicate the proficiency test; Provide training; Implement; Clarify all legal requirements	Monitor and ensure that all legal and quality requirements are fulfilled
Supplies Area	Set flow of inputs; Ensure assistance to all areas	Monitor the expiration dates of the lots in stock; Predict seasonality use
Clinical Engineering	Provide the electrical facilities; Determine the replacement of defective equipment	Install; Register; Replace
Information Technology	Evaluate the possibility of using existing resources (interfacing with the HIS or LIS) or the development of other resources	Monitor implemented systems (corrective and preventive actions)
Health Training	Choose best tool for user's training	Keep content updated; Register; Monitor retraining
Purchase Area	Negotiating prices; Negotiate payment terms	Maintenance of contracts
Nursing	Indicate key personnel to support implementation; Indicate difficulties; Attend training; Comply with the concept of performing tests	Attend retraining; Indicate problems; Perform procedures according to the guidelines
Commercial Area	Negotiate with insurance providers and payment sources	Ensure coverage for procedures
Management of hospitalized patients at the institution	Distribute expenses by cost centers	Ensure compliance with the agreed rules
Safety, Hospital-Acquired Infection and Diabetes Committees	Assess impacts preventively	Contribute to achieving the objectives
Clinical Staff	Be involved and informed	Receive progress reports

carrying out operational processes
- Identify and determine opportunities for improvement

The internal audit will seek to ascertain whether the laboratory medicine service or the unit submitted to inspection is performing their quality control activities efficiently.

1.5 Costs of POCT

Due to its low demand, POCT is at a disadvantage compared to conventional equipment testing in terms of its costs, since, as it is known, cost is inversely proportional to the volume of use. It is important that healthcare companies seek to understand the purpose of using POCT, since the financial impact may be completely different depending on the intended objective, i.e., it is fundamental to investigate whether there is, in fact, a clinical need for the use of this modality of diagnostic equipment, since its cost, including inputs and reagents, usually exceeds the cost of performing the same tests in a routine laboratory [17].

Conventional tests are carried out in outpatient laboratories, which, presumably, have a considerably larger physical space than what is required for POCT, which can be accommodated on a bench or even on a doctor's table. Within the structure of a conventional laboratory, pre-analytical and post-analytical areas need to be added to the analysis process, and support areas, such as billing, financial, personnel department, human resources, and others that require specific labors, are also needed. In the case of POCT, there are hidden costs that need to be evaluated, such as local laboratory support, user training, and preventive maintenance. For a cost comparison between the two modalities, the main point to evaluate is the need, not just the test in question. By definition, POCT is performed near or at the bedside,

Table 2. Example of tests provided by Point-of-Care Testing.

Analyte/Speciality	Biological material to be analyzed	Technology used	Manufacturer
Glucose Monitoring/Biochemistry	Blood	Reagent Strip Dry Chemistry	Abbott Laboratories
Nitrite/Urinalysis	Urine	Strip Reagent Dry Chemistry	Roche Diagnostics
Influenza A&B/Virology	Nasal secretion Nasal swab	Immunochromatographic test	AlereTM
Prothrombin/Coagulation Time	Whole capillary blood	Electrochemistry (Coagcheck XS Pro)	Roche Diagnostics
Troponin I/Cardiac Marker-Biochemistry	EDTA blood	Fluorometric Immunoassay (AQT90 Flex)	Radiometer
pO2, pCO2: Blood gases/Emergency Room	Blood heparin	ISE: Amperometry and Potentiometry (ABL 800 Flex)	Radiometer
Rapid test for detection of Lancefield beta-hemolytic group B streptococcus antigen/CSF- Microbiology	CSF	Latex Agglutination (BBL Streptocard Acid Latex Test)	Becton, Dickinson and Company
Screening of Methicillin-Resistant Staphylococcus aureus (MRSA)/Microbiology - Molecular Biology	Nasal secretion samples	Nucleic acid sequence-based amplification (NucliSENS EasyQ MRSA)	BioMérieux
Clostridium difficile/Parasitology - Molecular Biology	Stool - Swab	Polymerase chain reaction (PCR)-based POCT (GeneXpert®)	Cepheid
IgG antibody to H. pylori/ Gastroenterology - Immunology	Serum	Immunochromatographic Test (ACONO H. pylori Rapid Test Strip)	Acon Laboratories, Inc.

and its result gives the physician the possibility of promptly intervening in the treatment, thus ensuring a greater effectiveness in the diagnostic procedure. POTCs are therefore very useful in situations where a delay in outcomes could have a significant impact on the patient [18].

Considering an intensive care unit, where the time of analysis may directly influence the physician's conduct and, consequently, the patient's response to treatment, POCT is an interesting option. Generally, the preparation of these equipment to start the routine is faster than the equipment used in an outpatient laboratory, which may need anywhere from minutes to hours to get into operation.

The processing time of POCT takes, on average, 284 seconds, while the time required to send a sample to the central laboratory can take 486 seconds if a pneumatic tube is used or 603 seconds if it is carried out by an individual [1,19,20].

In the case of the ICU, the labor force used for POCT may be the same personnel that are already in place, e.g., the nursing team and the intensivist physician. Consequently, for the cost evaluation, these professsionals would not be considered in the first instance, since, as mentioned earlier, they are already allocated. However, this allocation is a frequent misconception; the correct allocation considers a fraction of the cost of these professionals into the costs of POCT, since these professionals would not otherwise be operating the equipment, which might lead to a need for new hires to bridge the gap in daily work. On the other hand, in the case of outpatient laboratories, the corresponding labor force tends to be much more extensive, even in hospital units, where it would be necessary to consider professionals who are directly or indirectly involved in the operation, such as receptionists, collectors, administrative personnel, and others. In POCT cost evaluations, personal expenditures are the most relevant, accounting for 2/3 of the total expenditures. However, in a comparative analysis of the total laboratory flow in POCT and a centralized laboratory, the former demonstrates a simpler and more dynamic flow than the latter.

The use of POCT, which has a turnaround time of approximately 5 minutes, becomes meaningless if, for any reason, the delivery of the result takes as many minutes to reach the doctor. Turnaround time is a challenge for the central laboratories and can be solved with POCT. Constant technological advances, combined with minia-

turization, have been increasing the set of analytical possibilities in POCT. The cost increase for POCT tends to be compensated by the reduction in turnaround time.

Consider an example in which a kit with one hundred tests can be used, at a cost of US $250.00, and thirty of these tests are needed to perform quality control and calibration. The cost of each test would be US $2.50 (US $250.00/one hundred tests), which becomes US $3.57 (US $250.00/seventy tests), since it is only possible to use seventy of the one hundred tests to release patient results. The costs related to labor and other consumables must be added to this amount to reach the total cost of the test per test released (patient) [21].

CONCLUSION

From a clinical point of view, some questions may be important in the selection of a new POCT-based analytical system, for example, the type of patient who will benefit from this acquisition, the range of analytes that are accessible using this technology, how the set of generated results will be used, and what the benefits will be to the patients.

For the technologies that are currently available in POCT to be applied clinically, a few critical issues need to be addressed, such as the standardization of operational procedures and the standardization of units of expression of results. In some institutions, the equipment is handled by professionals of different technical backgrounds; without the proper laboratory experience, the operational details can be challenging. Doctors tend to quickly evaluate the results of the laboratory tests, focusing on numbers, and do not always look at the units in which the results are expressed. Some confusion may occur if there is an inadvertent change of units.

A wide variety of equipment, based on different technologies, is continually being tested in research laboratory benches, and some of the equipment is already in use under controlled conditions. Briefly, it is likely that most of this equipment will prove to be very useful in laboratory practice, and it will replace, with advantages, the current equipment. For this to happen, the new equipment must have additional features, such as very low weight and volume, mechanical and electrical robustness, intercommunication capability that is easily managed by non-specialists, or memory that allows maintenance of the operational data, including quality controls, analytical performance, and patient results. Additionally, self-monitoring capability with a menu of possible defects and, especially, locks and warning signals to resist misuse, will be increasingly desirable.

Declaration of Interest:
None.

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