

Improving Healthcare Accessibility through Point-of-Care Technologies

EDITED ON BEHALF OF THE NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING/NATIONAL HEART, LUNG, AND BLOOD INSTITUTE/NATIONAL SCIENCE FOUNDATION WORKSHOP FACULTY¹ BY CHRISTOPHER P. PRICE² and LARRY J. KRICKA^{3*}

Background: The NIH is committed to improving healthcare quality in the US and has set up initiatives to address problems such as the fragmented nature of healthcare provision. A hypothesis has been developed that testing closer to the point at which care is delivered may reduce fragmentation of care and improve outcomes.

Methods: The National Institute of Biomedical Imaging and Bioengineering (NIBIB), the NIH's National Heart, Lung, and Blood Institute, and the National Science Foundation sponsored a workshop, "Improving Health Care Accessibility through Point-of-Care Technologies," in April 2006. The workshop assessed the clinical needs and opportunities for point-of-care (POC) technologies in primary care, the home, and emergency medical services and reviewed minimally invasive and noninvasive testing, including imaging, and conventional testing based on sensor and lab-on-a-chip technologies. Emerging needs of informatics and telehealth and healthcare systems engineering were considered in the POC testing context. Additionally, implications of evidence-based decision-making were reviewed, particularly as it related to the challenges in producing reliable evidence, undertaking regulation, implementing evidence responsibly, and integrating evidence into health policy.

Results: Many testing procedures were considered to be valuable in the clinical settings discussed. Technological solutions were proposed to meet these needs, as well as the practical requirements around clinical process change and regulation. From these considerations, a series of recommendations was formulated for development of POC technologies based on input from the symposium attendees.

Conclusion: NIBIB has developed a funding initiative to establish a Point-of-Care Technologies Research Network that will work to bridge the technology/clinical gap and provide the partnerships necessary for the application of technologies to pressing clinical needs in POC testing.

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Recent reports have pointed out that, despite significant advances in medical technologies, there has been a lack of corresponding improvement in the quality of healthcare delivery in the US due to "disconnected processes" and the gap between technology, knowledge, and investment on the one hand and the quality of care on the other (1–3). One approach to dealing effectively with these failures has been a systems-engineering approach to the organization and management of healthcare services, which involves "the design, implementation, and control of interacting components or subsystems" (4). The goal of applying systems-engineering concepts is to enable the components to work together in a way that improves the performance of the system as a whole, i.e., the delivery of healthcare that is safe, effective, timely, patient centered, efficient, and equitable. Although systems-engineering concepts have been used effectively in manufacturing and service-related industries, application to the healthcare sector has presented challenges due to the fragmented structure of the system and industry-specific regulatory and reimbursement issues.

One aspect of systems engineering is the utilization of information and communications technologies to opti-

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mize system functionality, thereby enabling patient-centered care across various healthcare settings. This process includes the potential for delivering diagnostic services at the point of care (POC),⁴ with the potential to significantly change the way care is delivered. The NIH [through the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and the National Heart, Lung, and Blood Institute] and the National Science Foundation sought to determine how POC technologies might contribute to the vision of improving healthcare accessibility and delivery through a workshop held in April 2006 entitled "Improving Health Care Accessibility through Point-of-Care Technologies." The 4 main challenges are (a) producing robust technology, (b) ensuring quality of operation, (c) resourcing of POC testing (staffing and reimbursement), and (d) changing practice to realize benefits. This review represents the deliberations of the workshop and the recommendations provided by participants for advancing POC testing.

Clinical Need for POC Technologies

PRIMARY CARE

Primary care needs that will drive innovation in POC testing are to improve (a) quality of care, (b) health outcomes, and (c) the financial feasibility of such practices. Improved POC testing offers the potential to expand the scope of practice of primary care providers and thereby bring care closer to the 1st point of contact in both temporal and organizational dimensions.

An informal Internet survey of family physicians in the US was conducted to ascertain their thinking about expanding POC testing in their offices (147 responses, a response rate of 29.4%), including office laboratory testing, imaging, and home monitoring. They were asked how likely it is that a particular test or imaging/home monitoring device would be used in the primary care office if it were easy to perform, reliable, and inexpensive. There was overwhelming support for expansion of office-based testing. Their feedback is summarized in Table 1. In the area of imaging-related applications, questions were asked about the use of office-based ultrasound likely to be used in the primary care setting (Table 2). For home monitoring, respondents were likely/very likely to use technology that would allow monitoring from their offices of patients' blood glucose concentrations (92%), international normalized ratios (90%), and body weights (83%).

⁴ Nonstandard abbreviations: POC, point of care; NIBIB, National Institute of Biomedical Imaging and Bioengineering; EHR, electronic health record; DMO, disease management organization; EMS, emergency medical services; IVD, in vitro diagnostic device; MIB, medical information bus; HCSE, health-care systems engineering; CMS, Center for Medical Services; NCD, national coverage determination; POCT, Point-of-Care Technologies Research Network.

Table 1. Laboratory tests family physicians would use in their offices, if cost-effective.

Chemistries	HbA1c, international normalized ratio, microalbumin, lipid profiles - very popular. Others - brain natriuretic peptide, troponin, creatine kinase, D-dimer, drug screens, uric acid, electrolytes, glucose, hemoglobin/hematocrit, creatinine, aspartate transaminase, hepatic profile, amylase, lipase, erythrocyte sedimentation rate, complete blood count, thyroid-stimulating hormone, lead level, bilirubin, B-12, fructosamine, high-sensitivity C-reactive protein, quantitative beta, human chorionic gonadotrophin, prostate-specific antigen
Infectious diseases	Tests to distinguish bacterial from viral infections, influenza, mononucleosis - very popular. Others - urine culture, HIV, respiratory syncytial virus, <i>Clostridium difficile</i> , rotavirus, bacterial vaginosis test, trichomonas, <i>Helicobacter pylori</i> , chlamydia, gonorrhea, herpes, pertussis, human papilloma virus, group B streptococci, mycoplasma, onychomycosis

HOME CARE

Although institution-based care accounts for a considerable amount of the investment in health services, the past 20 years of transition to shortened stays means that individuals face most of their healthcare concerns at home and in the community. There are a variety of home healthcare processes and models.

Self-management. Self-management involves measurement of temperature, body weight, blood pressure, pregnancy, and blood glucose. Results are interpreted by the user or family members, and occasionally the results may be transmitted (e.g., by telephone) to people outside the home for interpretation. This management is predominantly paper-based, but it is becoming increasingly elec-

Table 2. Conditions for which family physicians would use office ultrasound, if cost-effective.^a

Indication	Likely or very likely to use ultrasound for this indication, %
Diagnosis of peripheral vascular disease	79
Screening for abdominal aortic aneurysm	73
Screening for carotid stenosis	68
Measurement of cardiac ejection fraction	59
Evaluation of breast masses	60
Pregnancy dating	58

^a Other potential uses for office ultrasound: detection of cutaneous, subcutaneous, and soft tissue masses; deep vein thrombosis; gallbladder, scrotal, prostate, pelvic masses; endometrial stripe thickness; renal, bladder, abdomen, venous Doppler, obstetric indications; thyroid nodules; joints; liver.

tronic in the form of personal or electronic health records (EHRs). Home monitoring is explicitly included as one data source that should be supported by personal health records (5).

Remote familial care. Remote familial care by grown children provides a way to "check in" on remote parents that may involve POC testing and/or remote monitoring technologies.

Home nursing. Home nursing commonly uses POC testing devices, including glucose meters, blood pressure monitors, scales, coagulation meters, spirometers, and thermometers. Home telemedicine devices, often combining videoconferencing and POC testing, are being used to replace a fraction of home nursing visits (6), while also avoiding costly hospital referrals.

Disease management organizations. Disease management organizations (DMOs) operate programs designed to achieve the 6 Institute of Medicine (2) objectives for care, namely safe, effective, equitable, patient-centered, timely, and efficient. They offer support for the primary care/patient relationship; a patient-centered plan of care; prevention of exacerbations and complications utilizing risk assessment and evidence-based practice guidelines; interdisciplinary collaboration and feedback loops; patient empowerment strategies; as well as a robust evaluation program (7). DMO programs encompass both prevalent (e.g., diabetes and heart failure) and complex diseases (e.g., multiple sclerosis) for which opportunities exist for improvement in the quality of care.

POC testing data integration supports self-care, patient/caregiver education, and timely, efficient primary care and care plan changes to minimize adverse events. Strategies include aggressive clinical management and maximization of self-care efficacy (e.g., improved medication adherence, symptom management, and action for early clinical changes). An example, reported by Lehmann et al. (8), demonstrated that telehealth technology for the management of patients with chronic heart failure led to a 41% reduction in overall utilization of health resources, 43% decrease in physician office visits, 33% decrease in emergency department visits, and 29% decrease in hospitalization.

Chronic care model. The chronic care model relies on extension of the capabilities of existing clinicians through the development of multidisciplinary teams, rather than through contracts to 3rd-party DMOs. The chronic care model approach is similar to DMOs in using POC testing (patients trained to monitor their own medical conditions, interpret the results, and change therapy) and remote monitoring for earlier detection of changes in the patients' conditions.

Remote consultation. An often-cited future for home POC testing is the "electronic house call." For this vision to become reality, POC testing devices will need to be developed to support it. These methods will differ from most POC testing devices because they will be used very rarely, and will probably need to cover a large panel of commonly needed diagnostic targets.

EMERGENCY MEDICAL SERVICES

The level of an emergency medical services (EMS) provider determines the capability and equipment they are able to use. The 1st responder is able to provide an initial level of care that includes simple airway control with positioning maneuvers, bag-valve-mask breathing support, simple splinting and bleeding control, cardiopulmonary resuscitation, and automatic external defibrillation. The basic emergency medical technician has the same capability as the 1st responder and can provide additional airway support with an invasive Combitube airway. The paramedic performs more advanced procedures, e.g., 12-lead electrocardiograms, pulse oximetry, and CO₂ monitoring and administers oral, intravenous, and introsseous medications.

More highly trained EMS personnel may provide specialized care. The critical care paramedic is trained to use many cardiac and vasoactive drip medications and ventilators used primarily for interhospital patient care. Various types of air medical providers may be trained to handle the interfacility transport of stable and unstable patients beyond the scope of practice of most ground providers (9,10).

Environment is a significant factor in the performance of EMS practice, as it is frequently performed in outdoor and vehicle environments that introduce temperature extremes, rain and humidity, low- and high-level light extremes, and movements and vibrations that can impede the performance of electronic monitoring and diagnostic equipment.

For POC testing to be useful in EMS, (a) the technology must provide a rapid assessment; (b) the information obtained must be able to impact either the provider or patient safety or provide information useful in determining appropriate treatment or triage; (c) the cost must not be prohibitive, because EMS reimbursement is fixed per patient and is not itemized based on the number or complexity of procedures or treatments; and (d) testing must be on site. The opportunities for POC testing include scene analysis, oximetry, and imaging in patient assessment together with assessment of other critical parameters, e.g., potassium, cardiac and stroke markers, and electrocardiogram.

Technologies for POC Testing

Numerous new technologies are claimed to be useful for POC testing, but often it is difficult to assess the true utility of such technologies, especially if assessment was limited to proof-of-concept experiments with solutions of

analyte in a buffer that do not reflect the complexity of blood or plasma specimens. There is a need for a mechanism that would provide investigators with access to clinical specimens and an appreciation of the real-world needs of the clinical POC testing environment, including components of the user interface, such as positive operator identification and quality-control lockout, data storage, and connectivity. Hospitals have proved to be grueling environments for POC tests and test devices and have revealed numerous failings in devices designed to be foolproof. Early exposure to the rigors of this environment will translate into more robust POC technology designs.

IN VITRO TESTING

The microelectronics industry provides a number of attractive features and capabilities that may help shape the evolution of the next generation of POC devices that combine sample collection, analysis, and reporting of results into a robust integrated testing structure, with a simple user interface. Such assays can be operated with fewer technological constraints and more quickly, making them amenable to POC testing (11–13).

Emerging examples include sensitized bead “microreactors” for pH, electrolytes, metal cations, sugars, toxins, proteins, antibodies, and oligonucleotides testing (14, 15) and miniaturized sensor systems based on a membrane capture element that is integrated into a fluidics structure for cell, spore, and bacteria separation and identification (16–18). Miniaturization has also enabled feedback loop-based, individualized, integrated medical systems, comprising an implanted sensor, battery, amplifier, processor, and actuator now in use in cardiac pacemakers and defibrillators. Drug-delivering medical feedback loops, comprising miniature sensors and drug pumps, would individualize timing and dose and thereby improve the effectiveness and safety of drugs. It is only a matter of time before “test and treat” feedback loops will be developed, e.g., for diabetes care.

Connectivity is of vital importance for POC testing, meaning connection to a laboratory information system, the hospital information system, and the electronic patient record. Standardization in this area was originally addressed in 1998 by the POC Testing Division of the AACC and members of the *in vitro* diagnostic device (IVD) industry, and by 2000 this had evolved into the Connectivity Industry Consortium that included representation by various standards development organizations (CLSI, ANSI Health Level 7, and IEEE) (19).

NONINVASIVE POC TECHNOLOGIES

Various technologies hold promise for noninvasive testing. These include ultrasound, low-cost magnetic resonance imaging and magnetic resonance spectroscopy, and optical sensing and imaging methods such as optoacoustics and optical coherence tomography. Noninvasive monitors, including electrocardiography, automated

sphygmomanometry, and pulse oximetry, are currently used in virtually all patients undergoing surgery, most patients in medical and surgical intensive care units, and many patients in nonspecialized nursing units. These 3 conventional, noninvasive monitors share 4 important characteristics that are essential for the clinical and commercial success of any new noninvasive or minimally invasive monitor: (a) a variable is measured that is strongly associated with morbidity or mortality (e.g., electrocardiography for heart rate and rhythm abnormalities); (b) the monitored variable must be one that can change relatively rapidly and warn of physiologic deterioration; (c) appropriate interventions must be available to modify a rapidly changing variable and reverse physiologic deterioration; and (d) it must be simple for health-care personnel to use with minimal instruction. Several promising targets for noninvasive monitoring meet the first 3 characteristics; the 4th characteristic requires effective collaboration between bioengineers and clinicians.

Several small, lightweight, and inexpensive POC echocardiography devices have recently become available (20), and a low-cost, benchtop, magnet system and microcoil array technology for imaging and monitoring has been developed (21, 22). Optoacoustics technologies use sensitive detection of laser-induced ultrasonic waves and may provide noninvasive, highly accurate, real-time and continuous measurement of total hemoglobin concentration, concentrations of hemoglobin derivatives, and other blood parameters (23, 24). Optical coherence tomography is based on detection of backscattered low-coherent light and may be feasible for glucose monitoring (25).

LOW-COST IMAGING USING POC TECHNOLOGIES

Recent advances in automated image acquisition and analysis can provide attractive approaches for screening in settings without the normal infrastructure and trained personnel. For instance, Sun et al. (26) have developed technology to measure DNA ploidy to assist cytotechnologists in cervical cancer screening.

Advances in micromanufacturing provide further opportunities for cost reduction in POC imaging systems. Low-cost, high-resolution clinical imaging based on microfabricated components (e.g., injection-molded plastic miniature objective lens) is being explored for detection of early cervical cancer (27).

Informatics and Telehealth

The gathering, recording, and communication of structured and coded data into an understandable electronic format are now recognized as crucial to improving health-care. However, converting to an EHR is challenging. Which data elements should be collected and at what frequency has not yet been determined. The ultimate goal is to establish automated data acquisition techniques using POC technologies coupled with telecommunications links to provide integrated healthcare records and EHRs. This process will facilitate the development of

computerized decision support tools that make use of structured and integrated records systems with consequent improvements in healthcare.

An overview of how medical care will likely be delivered in the future is presented in Fig. 1. Patient data and knowledge will automatically be integrated from multiple sources. As the patient data are collected, computerized decision support processes will be used to improve an individual patient's care but will also enable improvements in overall health outcomes and in public health. POC devices enable individuals to accurately, easily, and efficiently generate and collect healthcare data from the patient home, physician office, or hospital. For optimal patient care, data must be collected at all 3 sites and integrated into a clinical patient record. Data flow from the sites into an integrated patient database (denoted in Fig. 1 by the central, black circle), and as data are acquired from each of the sources, they pass through a computerized decision support system (which links current data with the knowledge/evidence base that determines the patient pathway, denoted in Fig. 1 by the outer, gray ring), which is activated as each data element is added to the integrated patient database. The conceptual model of data collection and decision support was taken from a similar operational model used for decades by the HELP hospital information system at LDS Hospital in Salt Lake City, Utah (28).

Once the required data set has been selected, integrating the medical data into a comprehensive, integrated record is still difficult. Health Level 7 is a standard designed to help this; it is a set of ad hoc standards

developed to allow exchange of healthcare data between independent computer applications and healthcare systems (29). Using standard data definitions and data interchange standards, it is now becoming much easier to share medical data. Typically data entry is performed by people manually using a keyboard or touch screen, but more recently, the medical information bus (MIB) and other communication mechanisms have been used to automatically collect data from electronic POC devices; the MIB is now known as IEEE 1073. Using the MIB device data acquisition standard, data from bedside monitors, intravenous pumps, ventilators, and bedside laboratory testing devices can now be automatically collected in real time with speed and accuracy. The conceptual use of the MIB to gather data from POC devices is shown in the upper righthand corner of Fig. 1.

Once an integrated patient database is established, patients and caregivers can quickly and easily review and monitor clinical data. Applying computer-assisted decision support to the data-rich EHR is of great importance. Three recent examples have facilitated better use of antibiotics (30), reduction of medication errors (31), and public health surveillance at the 2002 Winter Olympic Games (32).

A SYSTEMS ENGINEERING PERSPECTIVE ON THE DELIVERY OF HEALTHCARE

As recognized through a recent study (4), a major reason for the shortfalls in US health today is the absence of involvement from systems engineers.

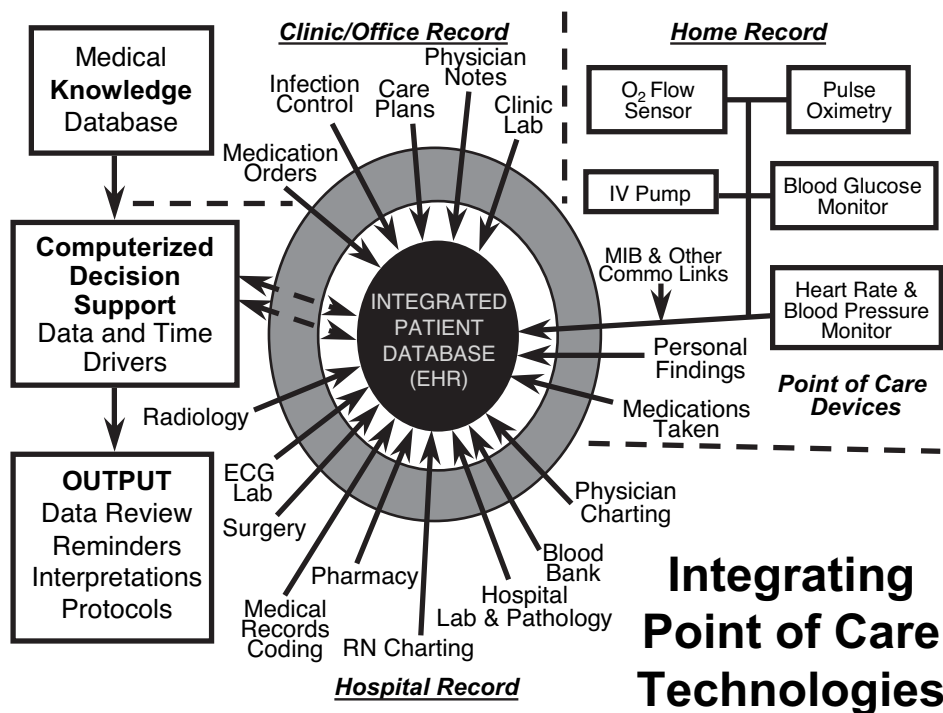


Fig. 1. A conceptual block diagram showing an EHR that has data flowing into it from 3 sources.

The home record includes data entered by the patient and also data automatically entered from POC devices such as a pulse oximeters, blood glucose monitors, and heart rate meters. In addition, patient data from physicians clinic/office record are also entered into the EHR. If the patient has had a hospital visit, the hospital record is also entered into the EHR. The left side of the diagram shows how medical knowledge in the form of rules and protocols are applied to each data element as it is stored into the EHR. By applying the medical knowledge using computerized decision support, patient data can be presented for review, provide reminders to patients and caregivers, provide interpretations of patient data, and drive protocols and guidelines to enhance patient care. The computerized decision support is activated whenever data are entered into the EHR (data driven) and at other designated times (time driven) to remind patients and caregivers to acquire data or take care actions such as taking a medication.

The focus of healthcare systems engineering (HCSE) is the integration of personnel, information, and communication technologies, facilities, and planning/control regimens that implement healthcare delivery. Thus at the macro level of systems operations, processes include human workers and patients in combination with technological components.

Most of the development and evaluation of proposed designs is done before they are implemented with the aid of predictive, computer-based modeling and assessment tools. Most such tools are descriptive, simulating or numerically estimating the performance of a given design under different conditions. Repeated application over proposed modifications can eventually lead to a system expected to give satisfactory performance. Even better, prescriptive modeling is possible in some problem settings; optimal choices can then be determined directly with the aid of computer search algorithms.

Intervention optimization. The goal is to choose delivery options that maximize outcomes and patient satisfaction while minimizing the clinical resources required. Whereas POC technologies enable healthcare delivery at the bedside, the home, or other distant sites, decision modeling can assist in a similar way with the numerous planning decisions that arise. How much medication should be administered and how fast? How frequently should rural patients report in with vital measurements, and when do they need to visit their provider? How do patients and their families balance choices near the end of life?

Tracking and assessment tools to identify shortfalls are one method for ensuring quality of service and minimization of risk. A wide variety of statistically based methods of this type are available from manufacturing and service industries. However, they require significant modification to meet the challenge in healthcare, because every patient brings different risks from comorbidities and other personal factors. Risk-adjusted quality measures are being developed to address such complications.

Operations management. Another very large domain of HCSE addresses the design, planning, and control of healthcare operations. They will have new importance with POC technologies. Facilities may have to be redesigned to accommodate those new tools and processes. Staffing will have to be planned to support them, and scheduling of operations will be impacted by fundamentally new modes of service delivery. Perhaps most important will be critical integration of information technology solutions such as bar coding and radio-frequency identification to track and control newly decentralized operations.

Nurses carry much of the burden in hospitals and large clinics, and this is exacerbated by time lost to foraging for equipment, supplies, medications, and test results and struggling with poorly designed information technology support systems. The promise of POC technologies is to

eliminate much of this waste by computerized tracking of materials and processes in addition to locating more of the care activity at the patient's bedside.

Enterprise design and value chains. At the highest level, healthcare is a complex network of interacting providers, including hospitals, ambulatory clinics, diagnostic centers, rehabilitation facilities, nursing homes, and home care, together with a variety of payers and suppliers. Distributed delivery with POC technologies is likely to complicate the already diverse mix. Similar challenges in other industries have produced a variety of predictive modeling tools, optimizing solvers to guide decisions about such issues of complex enterprise design.

Telehealth and home care. Healthcare delivery at remote sites via telecommunication and in patients' homes is likely to emerge as a major part of the provider system in coming decades because rural areas continue to struggle with provider shortages, patients like receiving care in their homes, and costs of institutionalized care grow ever more imposing. Advances in POC testing are expected to facilitate and accelerate this emerging trend.

Telehealth systems also create, perhaps more than any other delivery mode, challenges for the human factors engineering parts of HCSE. Safety issues are multiplied when care is delivered outside an institutional setting, particularly if it is administered by the patient or a caregiver. Teleinteractions with patients/caregivers having minimal computer literacy, language challenges, and cognitive limitations can be effective only if they are intensely designed and assessed using standard tools of human-computer interaction engineering.

Evidence-Based Decision Making

Policy decisions in healthcare are fundamentally based on improving health outcomes that maximize the benefit in the care of individual patients while minimizing risk, all at reasonable cost (33). Recent reviews have shown that much of the early POC testing literature focused on the technical performance of devices, although some outcomes data are now available (11, 12, 34, 35). In many cases the utility of the marker(s) will have been established initially using a laboratory-based service. Evidence of effectiveness should be based on establishing a link between the POC testing modality and the outcome. Guidance on study design can be found in other texts (36, 37).

Much of the above takes place in an experimental environment, and so translating the data into action in the routine setting, as well as translating guidelines into routine adherence to the new care pathway, may be the greatest challenge. This strategy can only be followed by assessing compliance through the use of clinical audits.

EVIDENCE AND REGULATORY APPROVAL

Technology advances medical practice and quality of care when it is judged to be beneficial to patients, aids

medical practitioners in the delivery of care, and meets the requirements of safety and efficacy in regulatory statutes. The FDA clears or approves most medical devices before they are commercially distributed. To obtain clearance, device sponsors (usually manufacturers) provide the FDA with a premarket submission that demonstrates the safety and efficacy of the device for its intended use. For an IVD, this means that sponsors provide data characterizing the analytical and clinical performance of the device. Clinical outcome studies are rarely required for IVDs.

Three basic elements are common to most FDA device reviews: (a) accuracy and reliability, (b) labeling, and (c) risk vs benefit. Although these discussions focus on IVDs, the concepts apply to many other types of devices.

Accuracy and reliability. To characterize real-world performance of a POC device, the claimed conditions for use should be replicated during validation studies (e.g., in an intensive care unit being operated by a nurse or in a home being operated by a lay user). Participants should represent the intended POC users, and studies should be done at a representative site. Operators should receive the same training they will receive when the device is marketed, and the labeling should be equivalent to the labeling of the final marketed product. Because the goal of the study is to demonstrate that users can operate the device and obtain results that are comparable to those obtained by laboratory professionals, study participants should perform each procedural step without assistance.

Another way the FDA assesses the reliability of a device is by evaluating the manufacturer's hazard analysis for the device that identifies all potential sources of error, describes how each potential error is mitigated, and validates the effectiveness of each mitigation. Stress studies (e.g., simulating an error condition and observing what happens) are often used to validate the effectiveness of safeguards designed into the device.

Labeling. The FDA reviews labeling to ensure that step-by-step instructions are clear, concise, and easy to follow. Labeling should be written at a grade level appropriate for the users (e.g., a 7th grade reading level is suggested for lay users). It should instruct users on how to recognize whether the device failed and describe what they should do if it failed. Labeling should be written before conducting the validation study so that it can be used during the study to verify its effectiveness. It should convey the limitations of the device and describe any follow-up steps that are needed.

Risk vs benefit. The 3rd review element is an analysis of the risks and benefits associated with using the device as intended. Examples of questions often considered are as follows:

- What is the medical benefit to having the device available at POC settings?
- Does the reduced turnaround time enable earlier intervention and treatment?
- Do test results encourage lay users to seek medical attention when it is needed?
- What is the impact of incorrect usage or device failure, or if performance is borderline?
- What is the consequence of a false-positive or false-negative result?
- Are patients unnecessarily admitted to the hospital?
- Do they receive extraneous treatments that may harm them?
- Can patients be discharged from the hospital when they have a life-threatening condition?
- What happens if treatment is delayed?

To answer these questions, the FDA considers information presented in the submission, literature or historical information, adverse event reports received for similar devices, or knowledge gained during prior reviews. When the risks and benefits are weighed, the effects on both individuals and the public must be evaluated. The device is cleared for marketing only if its benefits are greater than the risks.

INTEGRATING EVIDENCE INTO POLICY

The Center for Medical Services (CMS) makes national coverage determinations (NCDs) and bases the coverage determinations on whether the technology is deemed "reasonable and necessary" (38, 39).

For a technology to be considered for coverage, it must first fit into a benefit category defined in statute (e.g., hospital services, physician services, home health services).

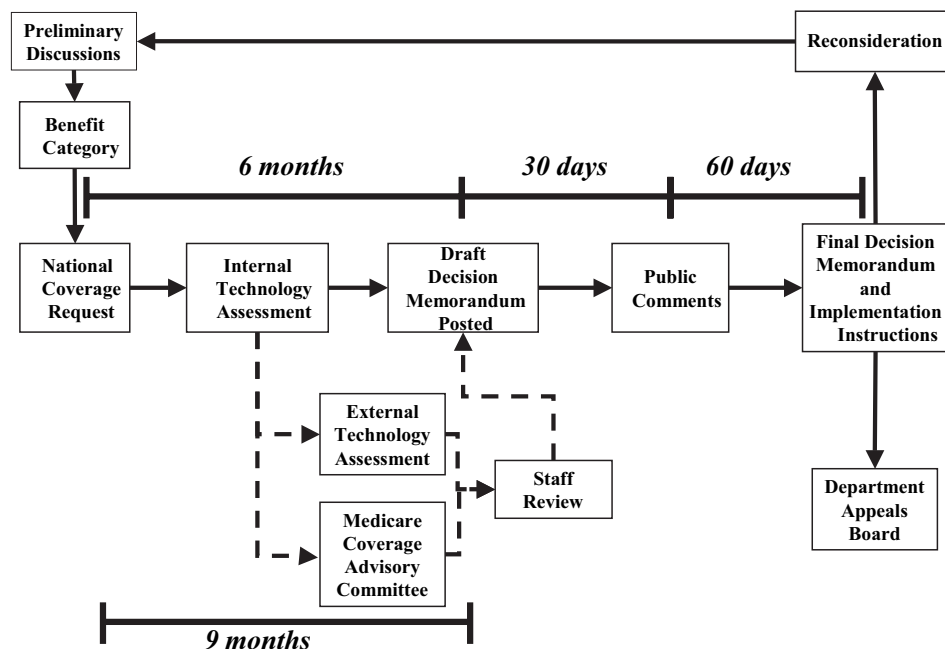
It must also be deemed reasonable and necessary to be covered. CMS has interpreted this to mean that there is sufficient evidence, generalizable to the Medicare population and the provider community, to conclude that the item or service improves health outcomes.

Ninety percent of coverage policy decisions are made at the local level by Medicare contractors. The 10% that are dealt with at the national level may have 1 of 3 outcomes, which are binding at all local levels: national coverage, national noncoverage, or national coverage with restrictions (specific populations, specific providers/facilities, evidence development).

An NCD may be opened for many reasons. An external party (e.g., Medicare beneficiary, manufacturer, provider) may request an NCD, or CMS may internally generate the request.

CMS may internally generate a request to develop an NCD in the interest of the general health and safety of Medicare beneficiaries, e.g., providers, patients, or other members of the public have raised significant questions about the health benefits of currently covered items or services (40).

Fig. 2. Summary of the Medicare national coverage process.



Neither cost nor cost-effectiveness is a factor CMS considers in making NCDs. In other words, the cost of a particular technology is not relevant in determining whether the technology improves health outcomes or should be covered for the Medicare population through an NCD. Reimbursement for an item that is covered by an NCD is assigned by another component of CMS. The coverage process is summarized in Fig. 2.

With all policy decisions, no matter how evidence based, there will be tensions. These tensions revolve around who makes the decisions and the judgments and opinions of individual patients and their physicians. By using evidence-based medicine as a framework within which coverage decisions are made, the agency hopes to be explicit, consistent, and transparent and allow for outside input while making sound decisions and producing NCDs that better the health of beneficiaries.

Summary and Recommendations

The following recommendations were developed on the basis of the presentations given at the workshop, together with the contributions made by the attendees, which included responses to 2 questions posed by the sponsoring agencies: Currently, what are the biggest challenges in advancing POC technologies? From a funding or program development perspective, what efforts do you suggest that the NIH and the National Science Foundation undertake to advance this field?

UNDERSTANDING THE NEEDS OF THE PATIENT, CLINICIAN, HEALTHCARE PROVIDER, AND HEALTHCARE PURCHASER

A common theme was the need for initiatives that would bring together technology developers and clinicians in an

effort to prioritize and match unmet clinical need and the potential benefit of new testing devices using the capabilities of emerging technologies. Additionally, exploring regulatory and reimbursement issues at an early stage was viewed as important to advancing the field. In this respect, there is a particular need to work closely with the FDA on appropriate pathways for instrument certification, and with CMS both to define high-cost diagnostic clusters that are particularly burdensome to US taxpayers and to publicize targeted test packages and their clinical and cost objectives.

UNDERSTANDING HOW POC TECHNOLOGIES WILL CHANGE THE PROCESS OF CARE

One of the key issues in healthcare organization and management is the “silo thinking” and “silo management” that exists, with too great an emphasis on the management of individual departments, rather than consideration of the whole organization—or patient journey (36). As healthcare becomes more patient focused in its approach, a greater emphasis needs to be placed on systems integration and support for approaches that bridge interdisciplinary communication gaps. These approaches must take into account healthcare relationships and healthcare information systems (e.g., standardizing connectivity and POC device output, integrating POC device output into EHRs).

STIMULATING RESEARCH SUPPORT FOR MULTIDISCIPLINARY RESEARCH AND TECHNOLOGY DEVELOPMENT IN POC DEVICES

Much of applied research in medicine is multidisciplinary translational research, but this culture applies equally to basic biomedical research and technology development,

especially with respect to the creation of POC technologies. As such, a recommendation was provided to increase support for cross-disciplinary work to establish teams of component developers (e.g., microfluidics, power sources, reagent storage, sensors, sample preparation, hybrid sensing/actuating devices, and algorithms) capable of designing fully integrated devices. A major aspect of this development is testing on clinical samples early in the process and considering connectivity (including standards and interoperability) and user interface issues. These latter issues speak to the challenges associated with integrating POC technologies into the healthcare system as a whole, with the need to include the clinical research and user perspective early in the technology development process. Additionally, with the requirement for low-cost technologies, there is a need to establish academic/industry partnerships that bridge the gap between technology discovery and commercialization, with a focus on more efficient design and manufacturing approaches for improvements in functionality and reduced costs. Last, a phased approach to funding of device development was advocated that would include input from the FDA, CMS, and relevant funding agencies regarding merits of further development (similar to the Department of Health and Human Services model for "Moving Medical Innovations Forward") (41).

TECHNICAL VALIDATION AND OUTCOME STUDIES

Biological samples represent some of the greatest sampling challenges, and one cannot stress too much the importance of demonstrating good technical performance with clinical samples. Once technical validation is complete, it is important to perform proper outcome studies in which the POC device is compared with the current standard of practice (e.g., laboratory-based test) to guide clinical decisions and actions; the preferred methodology would be a randomized controlled trial or similar study design, with the POC result being used to guide the clinical decision. These data can then be used to model the cost effectiveness and the change in the process of care, and in so doing identify the health outcome benefits. These data will help with revision of the care pathway and reimbursement decisions.

In response to these recommendations, the NIBIB has developed a funding initiative (42) that provides for the establishment of a Point-of-Care Technologies Research Network (POCT) that will work to bridge the technology/clinical gap and provide the partnerships and expertise necessary for the application of technologies, such as novel sensors, lab-on-a-chip devices, noninvasive and minimally invasive monitoring approaches, and imaging technologies, to pressing clinical needs in POC testing. A major technological aspect of this effort is a focus on integrating components and devices to create systems that have the necessary connectivity and usability within a given healthcare environment.

Potential centers comprising the network could be structured around themes that address the coupling of promising technologies with clinical needs and opportunities in specific healthcare settings such as primary care, home healthcare, emergency medicine, or healthcare in low-resource areas. Alternatively, POCT centers could be focused on disease groupings, for which POC technologies have significant potential to address future healthcare challenges, such as cardiovascular and neurological disease. It is expected that the structure of each POCT center will take into account the full range of technology and clinical partnerships necessary to facilitate the identification and integration of enabling technologies into devices that address defined clinical needs and healthcare delivery challenges that are specific to the intended use in a given care setting.

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Appendix

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