RESEARCH PAPER

Artificial Intelligence–Driven Biosensors for Point-of-Care Diagnostics: Integrating Electrochemistry, Biotechnology, and Clinical Laboratory Applications

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Abstract

Artificial intelligence (AI) has emerged as a pivotal force driving the evolution of point-of-care (POC) diagnostics, enabling quick and precise disease detection on the periphery away from the centralized clinical laboratory. This review explores that intersection, between three disciplines—electrochemistry that provides the transduction physics of the predominant class of biosensors, biotechnology that provides the biological recognition elements that confer biological specificity, and clinical laboratory science that provides the diagnostic and regulatory requirements any device must fulfill. The review summarizes the application of machine learning (ML) and deep learning (DL) at various stages of the bio sensing pipeline, with a focus on the latest advances, including the design and optimization of recognition molecules and nanomaterials, processing of noisy and multidimensional electrochemical signals including voltammetry and impedance spectra, enabling multiplex and continuous measurement, and translating raw sensor output to clinical decision making. Key applications, including those for diabetes management, cardiovascular biomarker detection, infectious disease diagnosis, and cancer screening, and the development of wearable and smartphone-integrated platforms and their connection to cloud computing and the IoT, are discussed. Next, the major challenges to clinical translation—including lack of data, imbalanced data, model over fitting and lack of external validation, the "black box" interpretation issue, regulatory uncertainty for adaptive algorithms, and data privacy—are discussed and are proposed as the current rate limiting steps. The dedicated analysis places the technology in the health system of Pakistan and other low and middle-income countries (LMICs) where there is the greatest need for affordable POC diagnostics powered by AI, due to a scarcity of clinicians, laboratories, and, of course, diabetes, hepatitis, tuberculosis, and dengue—among the most pressing health challenges; but where there are also the most significant gaps in data, infrastructure, and governance. It concludes that while AI-powered biosensors have moved out of the proof-of-concept stage and are becoming a reality in the clinic, to fully achieve their potential—especially in resource-constrained environments—the process of creating standardized datasets, building explainable and robust models, designing fit-for-purpose regulatory frameworks, and establishing locally-validated sensors must all work together.

Keywords: biosensors, artificial intelligence, machine learning, point-of-care diagnostics, electrochemistry, clinical laboratory, wearable sensors, low-resource settings

How to cite this article: Sabahat Ali Sheikh, Sania Anwaar. Artificial Intelligence–Driven Biosensors for Point-of-Care Diagnostics: Integrating Electrochemistry, Biotechnology, and Clinical Laboratory Applications. Int J Drug Deliv Technol. 2026;16(79s):566-574. DOI: 10.25258/ijddt.16.79s.109.

1. Introduction

Traditional medical diagnostics have been firmly in the centralized clinical lab, where they are sophisticated, accurate, quality controlled, but often slow, expensive and far removed from the patients in need. To address these challenges, point-of-care (POC) diagnostics, which are tests conducted at or near the point of patient care and produce results in a matter of minutes, were developed, and proved useful in a global pandemic when the urgent need was to get away from a laboratory-only testing paradigm to a rapid, decentralized, and accessible platform, as in the case of COVID-19 (Han et al., 2025). The biosensor is the central component of many POC devices, which is an analytical device that combines a biological recognition element with a physical transducer that transforms the molecular recognition event into a measurable signal (Bocan et al., 2025; Díaz-Fernández, 2025).

Biosensors are an attractive combination of characteristics in decentralized testing in terms of speed, cost, and ease of use, size, sensitivity and portability for their electrochemical form in particular (Bocan et al., 2025). But these same devices have always been plagued by a number of ongoing challenges that have hindered the path to commercialization. The data obtained from modern biochemical sensors are multidimensional and

nonlinear, often multimodal; chemically complex and noisy biological samples like blood, saliva, and sweat exist; manufacturing variability between different sensors compromises the reproducibility of the results; and interfering species in real matrices interfere with the specificity of any diagnosis (Kaur et al., 2025). At the core of these are issues of signal complexity and data interpretation – the type of problem which AI excels.

Incorporation of AI (Artificial Intelligence) technology, particularly its subfields of ML (Machine learning) and DL (Deep learning), into the biosensor technology has therefore become one of the most vibrant areas of research in the field of analytical and biomedical science. AI-powered systems could offer the ability to recognize patterns in electrochemical signals that are not discernible by traditional analytical techniques, reduce background noise and interference, correct for sensor drift and variation, and convert raw, physicochemical data into quantitative, clinically actionable results (Kaur et al., 2025; Chen et al., 2025). Nowadays, review articles throughout the field report on the use of ML across the entire biosensing process from designing the molecular recognition mechanisms to the final clinical decision (Bocan et al., 2025; Zhang et al., 2025).

The very nature of this activity is one that cannot be grasped within the boundaries of any single discipline – it is this that makes it truly unique and is the motivation for the present review. An AI-powered POC biosensor is a three-field integrated product in an irreducibly interconnected manner. The transduction physics of the most commonly used class of biosensors – the electrode materials, the redox chemistry and the voltammetric, amperometric and impedimetric methods that link a biological binding event to an electrical current or change in electrical impedance – are provided by electrochemistry. The specificity that defines a biosensor from a chemical sensor is provided by the biological recognition elements such as enzymes, antibodies, nucleic-acid aptamers, and more recently, CRISPR-associated proteins, provided by the field of biotechnology. Before any device can be used to direct the care of patients, it must meet the clinical laboratory science expectation of diagnostic frameworks, reference standards, quality-control regimes and regulatory expectations. AI is the glue that now more and more connects these together, optimizes the chemistry, interprets the biology and delivers the clinical output.

This review brings together the recent literature on this tri-disciplinary approach to develop AI-enabled biosensors for POC diagnostics. It aims at four things: presenting foundational principles at the intersection of electrochemistry, biotechnology and clinical diagnostics; providing a comprehensive overview of ML/DL applications throughout the bio sensing pipeline; highlighting key applications in the clinical domain and the advent of wearable and connected platforms; and critically reviewing challenges towards clinical translation and the context of the entire enterprise in the specific opportunities and constraints of low and middle-income countries (LMICs), with a special focus on Pakistan. The review does so to fill a gap in the literature, as while excellent recent reviews exist on AI in electrochemical sensing (Bocan et al., 2025; Kaur et al., 2025), optical sensing (Chen et al., 2025) and POC testing in general (Han et al., 2025), a review explicitly focusing on the intersection between the three founding disciplines and on the implications of the technology for resource-limited health systems is lacking.

2. Methodology

This is a narrative-integrative review, which is suitable for the purpose of this synthesis of a rapidly changing, multidisciplinary literature to provide a conceptual framework instead of addressing a narrowly formulated quantitative question. Literature was obtained by structured search in four databases (PubMed, Web of Science, Scopus, and Google Scholar) from 2015 to 2026, focusing on 2023–2026 to include the latest advancements. The search terms were used to combine the concept clusters "artificial intelligence", "machine learning", "deep learning" and "biosensor", "electrochemical sensor", "point-of-care", "diagnostics", "wearable sensor", and "aptameric" in a Boolean fashion.

Sources were selected based on peer-review status, journal prestige, regency, and relevance to the tri-disciplinary focus with high quality review articles and primary studies appearing in analytical-chemistry, biosensor and biomedical journals being preferred. The goal of this conceptual synthesis is not to conduct a formal effect-size pooling and the results are grouped thematically according to the biosensing pipeline and clinical application areas. This design has limitations inherent in narrative reviews, such as the ability to select which sources to include and not formulating a systematic analysis of risk of bias, which are recognized here and addressed through clear statements about sources and drawing conclusions where the independent sources agree.

The Three Converging Disciplines at the foundation stage.

2.1 The Electrochemical Basis of Biosensing

A biosensor is composed of two basic components: the bio recognition element (selective interaction with the target analyte) and the transducer (transduction of the bio recognition event into a measurable signal) (Díaz-Fernández, 2025). Transduction can be optical, mechanical, thermal or electrochemical; electrochemical transduction has taken the lead in

POC applications due to its low cost, miniaturization, and its compatibility with mass-manufactural screen-printed electrodes and the direct applicability to portable electronic readout (Bocan et al., 2025). The blood glucose meter—an amperometric enzyme electrode—has been and is the prototype and the commercial representative of the whole field.

Electrochemical biosensors are typically grouped on the basis of the principle used on which the biosensor is based. Amperometric sensors are those in which the current resulting from the oxidation or reduction of an electroactive species is measured at a fixed applied potential, such as used in glucose oxidase–based glucose sensing. Voltammetric methods such as cyclic and differential-pulse voltammetry scan the potential and measure the current, which gives a very extensive signal, with the position of the peaks representing the identity of the analytic and the height of the peaks representing the concentration. Potentiometric sensors provide a voltage signal that is related to ion activity and electrochemical impedance spectroscopy (EIS) probes the interfacial properties of the electrode at a series of frequencies, providing a label-free pathway to binding event detection (Bocan et al., 2025). The sensitivity of all of these is dependent on the performance of the electrodes, and it is here that the chemistry of advanced nanomaterials such as carbon nanotubes, graphene, metal and metal-oxide nanoparticles, and conductive polymers has led to significant improvements in sensitivity through an increase in electroactive surface area, acceleration of the electron transfer, and increased scaffolds for the immobilization of recognition elements (Bocan et al., 2025; Kaur et al., 2025). The opportunity and need for AI-based analysis is created by the richness and complexity of signals generated by these techniques: multidimensional voltammograms and full impedance spectra.

2.2 Biotechnological recognition layer

The specificity, which distinguishes a biosensor from a generic chemical sensor, is provided by the biorecognition element and the biotechnology of these elements has changed considerably. The earliest recognition elements are enzymes, which provide catalytic signal amplification and are the basis of the glucose-sensing market, but are expensive and unstable. Antibodies have high affinity and specificity, but suffer similar problems with stability and cost to immunosensing. Chemically stable, inexpensive, easy to modify and applicable to a variety of targets from small molecules to proteins and whole cells, aptamers, short synthetic single-stranded DNA or RNA oligonucleotides, selected in vitro for high affinity to targets have become a focus of intense interest as recognition elements. More recently, CRISPR-associated proteins have also jumped into the biosensing realm; Cas-based systems that leverage the collateral cleavage activity of Cas12, Cas13, and Cas14 enzymes facilitate the specific detection of nucleic-acid targets, while new work has seen Cas14 coupled with aptamers to create hybrid sensors that detect protein biomarkers like cardiac troponin I (Kaur et al., 2025). As explained in Section 4, AI is starting to play a crucial role in engineering and selecting these elements, which make up the biotechnological toolkit of a biosensor that determines what a biosensor can detect.

2.3The Clinical Laboratory Standard

To be useful in patient care, a biosensor would have to meet the rigorous requirements of clinical laboratory medicine. Analytical performance: Sensitivity and specificity, limit of detection, dynamic range, precision and accuracy compared to a reference method; Clinical performance: Diagnostic sensitivity, specificity, positive and negative predictive values, and proven effect on clinical decisions. Biomarkers should be detectable in clinically relevant concentration range: for example, apt sensors for the cardiac marker, CK-MB, were able to detect the protein over a Nano molar range with a detection limit of sub-nanomolar concentrations in spiked human serum (Díaz-Fernández, 2025). Aside from analytics, clinical deployment requires reproducibility across device and operator, stability in the field, quality control and regulatory clearance. The central translation challenge of this field is that the same sensor that can give impressive results with curated samples in the lab should also give reliable results with messy samples in the real world, and among different manufacturing lots, and with the non-expert user (where the AI's ability to standardize and error-correct matters).

3. AI throughout the Biosensing Pipeline

AI's involvement in biosensing is not just one-time but rather a series of contributions along the development and operation of the system. These contributions are divided into design, signal processing, and interpretation stages and are summarized in recent comprehensive reviews (Bocan et al., 2025; Han et al., 2025) and this section follows this logic.

The relevant algorithms are discussed in this section.

Algorithms used in biosensing can be divided into two general categories. These are known as shallow or classical ML, and include supervised methods like support vector machines, random forests, k-nearest neighbors, linear regression, and logistic regression, as well as unsupervised methods, like principal component analysis and clustering, for classification (is a disease present?); regression (what is the concentration of the analytic?); and dimensionality reduction and pattern discovery (Bocan et al., 2025; Kaur et al., 2025). In the case of deep learning, they

use multilayered neural networks, in particular, convolutional neural networks (CNNs) for spatial and/or spectral data, such as sensor images, or voltammograms, and recurrent networks, and their descendants, for sequential data, such as continuous-monitoring time series (Han et al., 2025). Shallow methods are efficient in data and relatively easy to interpret and well suited to the small training sets common in biosensor studies, while deep methods are able to represent more complex signals, but require larger training sets and are more likely to overfit and obscure.

The assignment of algorithm family to biosensing task is not arbitrary but based on the structure of the data, as summarized in Table 1. Classical classifiers like support vector machines and random forests are commonly used when the analytical question is simple, such as binary or categorical classifications from a small number of engineered features, like peak heights in voltammetric measurements of diseased versus healthy samples. In the cases of quantitative estimation of the concentration of a certain analyte from a calibration relationship, regression methods, such as regularized linear models and ensemble regressors, are common. When the raw signal is high dimensional with unknown informative features, such as a complete voltammogram, an impedance spectrum or an image from a sensor, the features can be learned directly from the signal with a CNN, at the expense of increased data requirements. Where the data is sequential, such as the time series generated from continuous monitoring, recurrent and attention-based models are able to capture dependencies that are not possible in static models. Unsupervised methods lastly are used at upstream positions: PCA reduces correlated spectral variables to few dimensions that represent informative axes and clustering can be used to discover sample subgroups that do not have predefined labels.

Table 1

Map of the various Machine-Learning approaches to the different biosensing tasks

Biosensing task	Data structure	Typical algorithms	Key trade-off
Disease classification	Few engineered features	Support vector machines, random forests, k-nearest neighbors	Interpretable, data-efficient; limited for complex raw signals
Concentration estimation	Calibration features	Linear/regularized regression, ensemble regressors	Transparent; assumes informative features are known
Raw voltammogram/spectrum analysis	High-dimensional signal	Convolutional neural networks	Learns features automatically; needs large datasets
Continuous-monitoring interpretation	Time series	Recurrent/attention networks	Captures temporal patterns; complex, data-hungry
Dimensionality reduction, pattern discovery	Unlabeled multivariate	PCA, clustering	Reveals structure; not directly diagnostic

3.2 AI in the Development of Sensor and Recognition-Element Designs

AI contributions start even prior to construction of a sensor. More and more, ML models have been used to predict the binding behavior of candidate enzymes, antibodies, and aptamers that can serve as recognition molecules for the rational design of recognition molecules, and to optimize nanomaterials and electrochemical parameters, thereby decreasing the amount of experimental trial and error (Chen et al., 2025). In electrochemical systems in particular, ML has been applied to optimize operating parameters and electrode compositions to achieve the best analytical performance and reviews on AI-assisted electrochemical sensing applications have included target detection such as material optimization, sensor design, and multicomponent signal analysis (Chen et al., 2025). This design stage position is directly related to the general AI revolution in molecular and protein modeling, and is the only position in which the recognition layer is designed in silica instead of the empirical fashion.

3.3 Interference Suppression and AI in Signal Processing

The most advanced and successful use of AI in biosensing is in signal processing. Electrochemical data (specifically voltammetric and impedance spectra) are information rich, high dimensional and subject to noise, drift and interference. These signals are used to find diagnostic patterns in the signal using ML algorithms that cannot be found by peak-picking or equivalent-circuit fitting. An alternative approach is to use raw impedance spectra as a representative advance, where the raw spectra are analysed directly by the DL models, rather than fitting a DL model to an analytical equivalent circuit: an example of this is the diagnosis of heart failure by DL detection of B-type natriuretic peptide (Bocan et al., 2025). ML has also been demonstrated to overcome sensor-to-sensor variations due to insufficient or non-specific interactions – in one impedimetric study the EIS data was directly processed by ML to allow reliable detection despite replicate-to-replicate variations that could not be overcome by conventional calibration (Bocan et al., 2025). Nowadays, the use of ML for electrochemical biosensing is fully recognized and the subject of comprehensive reviews, including the following modalities: biocatalytic, affinity-based, and bio receptor-free sensing, electrochemiluminescence, high throughput, and continuous monitoring (Bocan et al., 2025).

3.4 Quantitative Interpretation and AI in Multiplexing

But AI is the enabling technology for multiplexed detection—the ability to measure several analytic simultaneously—since it can help to separate the signals from multiple recognition events on a single platform. In POC testing in general, ML integrated into lateral-flow, vertical-flow, nucleic-acid-amplification, and imaging-based assays can help improve image and data analysis, signal processing, and quantitative interpretation, which are beyond simple yes/no results to multi-target, quantitative output (Han et al., 2025). In the field of serology, deep-learning algorithms have been used to get clinically relevant information from inexpensive hardware, such as paper-based multiplexed sensors that can simultaneously perform serological measurements and quantitative readouts for biomarkers (Han et al., 2025). This is a recurring, and strategically important theme that substitutes the computational sophistication for the hardware sophistication, especially in view of low-resource deployment.

5. Connected Platforms and Clinical Applications

5.1 Continuous Metabolic Monitoring and Diabetes.

It's most successful case study and most illustrative example of AI-driven transition from single-point to continuous and predictive monitoring is for diabetes management. Continuous glucose monitoring (CGM), the use of any wearable electrochemical sensor coupled with ML algorithms to report glucose levels and predict glucose excursions, has revolutionized beyond the classical glucose meter, providing "anticipatory" management instead of "reactive" management (as cited in the wearable-biosensor literature) (Jin et al., 2023). The monitoring of metabolites has been extended to continuous monitoring of lactate, ketones, etc. and it is possible to discriminate between glucose, lactate and ketones using multifunctional nanomaterials and electrochemical multiplexing techniques (Kaur et al., 2025). Another challenge in wearable metabolic sensing is the presence of motion artifacts; recent work published in the primary literature has shown the combination of high fidelity data acquisition coupled with edge processing to evaluate the ketogenic-health on the spot, an illustration of AI being integrated more into the sensor rather than just the cloud (Zhang et al., 2026).

5.2 Cardiovascular Biomarker Detection

For the diagnosis of cardiovascular disease, the analysis of cardiac markers like cardiac troponin I, CK-MB and B-type natriuretic peptide requires high sensitivity and speed in which minutes count and analytical sensitivity is a critical factor. Notable progress has been made in this area, thanks to biosensors empowered by AI: high-sensitivity troponin detection has been achieved with deep-learning-enhanced paper-based assays and vertical-flow assays with nanoparticle amplification, while dual-mode multiplexed optical sensors with deep-learning integration (Han et al., 2025) have been developed for POC cardiovascular diagnostics. As mentioned earlier, the CRISPR-aptameric hybrid sensors can be used for the extension of recognition toolbox to serum matrices for cardiac markers (Kaur et al., 2025). In all these examples, the idea is the same: by boosting the sensitivity and accuracy of lower-cost formats, AI brings the capabilities of central-laboratory immunoassay analyzers to the lower-cost formats.

5.3 Infectious Disease Diagnosis

The most apparent public-health benefit of POC testing is in the diagnosis of infectious disease, and the COVID-19 pandemic provided a clear impetus and evidence of the need for platforms that use AI to enhance next generation testing (Han et al., 2025). CRISPR-Cas diagnostic systems such as Cas12- and Cas13-based detection and Cas14-DETECTR integrated into paper-based microfluidic assays make it possible to rapidly and specifically detect a pathogen at the point of care (Kaur et al., 2025). For serological monitoring, as well as for serodiagnosis of diseases like Lyme disease, machine learning has been used to interpret multiplexed signals and enhance the accuracy

of the diagnosis by using a multiplexed paper-based immunoassay (Han et al., 2025). These capacities are of particular importance in the case of the high burden infectious diseases of the Global South.

5.4 Cancer Screening and Emerging Applications

Electrochemical biosensors have been long sought after for cancer diagnostics by the detection of circulating tumor markers, and now with the integration of AI, they are bringing us closer to non-invasive screening. In one illustrative embodiment, a platform was developed to functionalize commercially available glucose test strips with specific receptors and integrate them with a reusable printed circuit board for non-invasive detection of breast cancer based on salivary biomarkers, such as HER2 and CA15-3, which would be considered an example of frugal engineering complemented with a proper signal optimization (Díaz-Fernández, 2025). Non-invasive sampling, such as saliva, sweat and others with AI interpretation, are promising for screening at a population level.

5.5 Wearables, Smartphones, and the Internet of Things (IoT)

The future of the field is looking towards connectedness, continuity and decentralization in sensing. Wearable sensors equipped with embedded biosensors transmit data wirelessly (usually to a smartphone or cloud platform), where ML algorithms analyze the data, identify patterns, alert the user to any anomalies, and provide feedback, alerts, and health information. Multifunctional platforms have been shown to monitor multiple sweat parameters such as sweat pH, glucose, and skin hydration, while an increasing number of biosensors are capable of being connected to the Internet of Things and cloud computing for networked health monitoring on a large scale (Chen et al., 2025; Kaur et al., 2025). The use of smartphone based readers is especially important in terms of accessibility and extends the use of a common consumer device to a diagnostic device. These architectures, however, impose new requirements – on connectivity, data infrastructure and security of health data transmitted – that have a direct impact on their applicability in various settings and on the privacy and governance issues below.

Table 2 summarizes the application landscape explored in this section, detailing the mapping of clinical domains to representative target analytic, the recognition and transduction techniques used, and the specific contributions of AI. Reading across the table, it becomes clear that the basic integrative claim of the review is that in each of the domains, a biotechnological recognition element and an electrochemical (or optical) transducer provide the basic signal, and AI provides the layer that makes that signal clinically useful, such as increasing its effective sensitivity, resolving multiplexed outputs, predicting future states, or correcting for the limitations of low-cost hardware and non-expert use.

Table 2

AI Augmented Biosensor Applications in Clinical areas

Clinical domain	Representative targets	Recognition / transduction	Principal AI contribution
Diabetes / metabolic	Glucose, lactate, ketones	Enzyme / amperometric; wearable	Predictive forecasting; motion-artifact suppression; multiplex discrimination
Cardiovascular	Troponin I, CK-MB, BNP	Antibody, aptameric, CRISPR-aptamer / voltammetric, impedimetric, optical	Sensitivity amplification; raw-spectrum interpretation
Infectious disease	Viral/bacterial nucleic acids, antibodies	CRISPR-Cas, antibody / paper-based, microfluidic	Multiplex signal interpretation; quantitative readout from low-cost formats
Cancer screening	HER2, CA15-3, circulating markers	Antibody, receptor / functionalized strip, PCB	Signal optimization for non-invasive sampling

Note. Compiled from Han et al. (2025), Kaur et al. (2025), Chen et al. (2025), and Díaz-Fernández (2025). BNP = B-type natriuretic peptide; PCB = printed circuit board.

6. Barriers to Clinical Translation

Although they have been demonstrated in the lab for decades, few AI-based biosensors have made it to the routine clinical setting. It is now evident in the literature that the current challenges are no longer data primarily, but also in models, validation and governance (Han et al., 2025; Bocan et al., 2025).

6.1 The problem of Data Scarcity, Imbalance and Quality

However, the data that ML models are trained on are only as good as the data themselves, and biosensor data are often small, imbalanced, and non-standardized. Rare conditions can provide few positive examples, single-laboratory datasets can contain local idiosyncrasies, and there is a lack of standardized data formats that would allow combining data together in a way that would enable robust models (Han et al., 2025). A small set of training examples biases models, particularly deep ones, towards overfitting (memorizing the training data and not generalizing).

6.2 External validation, overfitting and generalization.

A related issue is the lack of external validation that can be seen throughout. There are many published models that have been claimed to perform well on data from the same type of device, operator, population or sample matrix as the training data, but do not perform as well with data from new devices, operators, populations or sample matrices. Even with an impressive performance in the literature, there is a risk that reported performance characteristics may significantly exceed clinical utility, unless they are validated in prospective clinical samples that have not been previously used. As repeatedly noted in the POC-testing literature, reported performances may significantly overestimate clinical utility if they are not validated on independent, real-world clinical samples.

6.3 The Interpretability Problem

Deep learning models are "black boxes", that is, they are models that make predictions without reasoning. This lack of transparency is a real impediment to trust and adoption in a clinical setting where clinicians need to justify their choices and make-inaccurate decisions can have grave consequences. Increasingly, there is a growing need to integrate explainable AI techniques that reveal which features influence a prediction for clinical acceptance, and this has yet to be completed in the case of biosensor systems (Bocan et al., 2025).

6.4 Regulatory Uncertainty

AI models (adaptive models that learn after deployment) conflict with the notion of a cleared device, and regulatory frameworks were designed for static devices. The validation, locking, monitoring and re-approval of learning algorithms are partially resolved in key regulatory areas, creating uncertainties and hindering commercialization efforts (Han et al., 2025). This uncertainty is further compounded in LMICs where regulatory capacity to regulate AI-enabled medical devices can be nascent.

6.5 Data Privacy and Security

The sensitive, personal data collected by connected biosensors, sent to smartphones and cloud servers, presents a pressing need for privacy, consent, security, and ownership issues (Chen et al., 2025). As biosensors get connected with IoT and cloud computing, thereby allowing for powerful networked monitoring, they create a larger attack surface and governance challenge, particularly when data-protection law is not well developed.

7. AI-Driven Biosensors in Low Resource Areas in Pakistan Context

The case for AI-powered POC biosensors is strongest right where the health system is weakest and the LMIC landscape (Pakistan is not the only relevant example) is unique in both accentuating the opportunity and focusing the barriers.

7.1 The Opportunity

LMICs like Pakistan face a diagnostic landscape with limited laboratory facilities located in urban centers, insufficient laboratory workforce and specialist clinicians, and a high burden of diseases that can be screened using biosensors. Pakistan has one of the highest incidence of diabetes globally, a high prevalence of chronic hepatitis B & C and is endemically affected by tuberculosis and recurrent dengue outbreaks that put a strain on seasonal capacity. In each of these cases, there is a need that is tangible and large-scale, to which a rapid, inexpensive, easy-to-use POC test without central laboratory or expert interpretation, is the answer. There are two aspects to this proposition where AI plays a key role. Firstly, it removes the barrier of the high cost of hardware by substituting computation for hardware, with the capability to generate clinically relevant quantitative results from a low-cost paper-based or strip-based format (Han et al., 2025). Second, it can be built into the device or a connected smart phone and thus, serve as a substitute for the lack of an expert human interpreter, effectively extending diagnostic expertise to the edge of the health system. Smartphone coupled biosensors are a realistic delivery vehicle as almost everyone in society, even those in low-income groups, have smartphones.

7.2 The overall assessment of the barriers is locally intensified.

The challenges of each of the translational barriers in Section 6 are heightened in the LMIC context. Data to train models representative of the population, pathogens and sample handling conditions are particularly scarce, and models trained with data from high income countries may not generalize well for local populations and disease variants - a specific example of the external-validation problem with equity implications. No connectivity or electrical-power reliability can be assumed, so architectures that rely on on-device ("edge") computation are preferred to relying on the cloud. There is limited regulatory oversight concerning the use of AI in diagnostics and data-protection governance is less fully developed,

increasing risks to citizens' privacy. Deliberate investment in interdisciplinary training is needed to build local capacity for development, validation, and maintenance of these systems, encompassing all of the above disciplines from electrochemistry to biotechnology to clinical-laboratory work that are brought together by this review.

7.3 A Realistic Path

A realistic agenda for Pakistan and similar contexts would therefore focus on: building local representative ethically governed databases of priority diseases; favoring data efficient models and architectures that are implementable in the field in terms of infrastructure; conducting validation studies with local clinical populations and avoiding depending on external claims; developing fit-for-purpose regulatory and data-governance frameworks, possibly regionally harmonized with other countries; investing in interdisciplinary human capital that spans chemistry, biotechnology and laboratory medicine. This is how AI powered biosensors can be viewed – not just as imported technology but as an area where local research can contribute and be relevant globally, based on local needs.

The discussion covers the current challenges and future prospects for the project.

Combining the above, there are a number of trajectories. This field is transitioning from single analytic detection to multiplex detection, from single time point to continuous monitoring, from cloud-based to embedded intelligence at the edges, and from lab demonstration to (inconsistently) clinical validation. The common strategic message is the replacement of hardware complexity with computational intelligence, both to make the technology more performant and cheaper, and the means by which the technology will enable the promise in resource constrained environments.

Some barriers have been identified and several future directions flow from those. The creation of common, consistent, and representative datasets is perhaps the highest leverage investment, conditioning model robustness, external validity and equity all in one. For trust to exist in the clinic, maturation and routine integration of explainable AI is a prerequisite. To be able to commercially use adaptive algorithms safely, the regulatory science must evolve into a framework that can regulate such algorithms, including through a post-market supervision of their performance. On-device and privacy-preserving computation, such as methods for training models across institutions without centralizing raw data, provides a pathway that can bridge the gap between networked learning and data protection and infrastructure limitations. Further, the ongoing intersection of the founding disciplines—aptamer design using AI and CRISPR design of recognition elements, super-sensitized electrochemical transduction via nanomaterials, and clinical validation with gold-standard assays—is poised to bring about the development of more specific, more sensitive, and more manufactural sensors.

This review should be restated as the limitations. It is a narrative-integrative synthesis and thus does not allow for the extraction of pooled quantitative estimates of diagnostic performance and the source selection is a result of a convergence-based approach in which the formal systematic-review protocol was not followed. The field is also fast-changing and provisional performance specs are given. Despite these caveats the review's key conclusions are given added confidence due to the convergence of the independent recent reviews of the promise and barriers.

Conclusion

Now, at the very heart of an AI-powered biosensor, three disciplines converge: electrochemistry to generate the electrical signal to report molecular events, biotechnology to provide the recognition elements to provide specificity, and clinical laboratory science to set the benchmark for a reliable diagnostic outcome – and machine-learning methods to design the chemistry, interpret the biology, and make the decision. Significant advancements are reported in the literature recently regarding the entire biosensing pipeline including rapid, substantial progress towards the design of recognition elements, nanomaterials, powerful signal processing to resolve diagnostic patterns from noisy electrochemical data, to compensate for device variability, to enable multiplexed and continuous measurement, and to translate raw signals into clinically actionable output across diabetes, cardiovascular disease, infectious disease, and cancer, increasingly through wearable and smartphone connected platforms.

This review's main thesis is that the "frontier" of the field has moved. Chemistry of the sensor is no longer the rate-limiting step: it is the data that power its algorithms, the robustness and interpretability of the models, the rigor of clinical validation, and the adequacy of regulatory and privacy governance. This is especially true in the low resource environments where the impact of the technology is most significant; for Pakistan and similar countries, AI-powered biosensors could bring diagnostic capability to the periphery of a health system, providing a substitute for the lack of laboratories and experts – but only if system-representative data, understandable and infrastructure-appropriate models, local validation and purpose-built governance are intentionally designed. Whether its benefits will reach those who need it most is less about the chemistry of the sensors and more

about making progress on data, validation, governance, and interdisciplinary investment—essential for a tri-disciplinary field—to make the transition from proof-of-concept to clinical reality.

References

Bocan, K. N., Nemati, E., Bogdan, P., & Mangharam, R. (2025). Machine-learning-aided advanced electrochemical biosensors. *Advanced Materials, 37*(33), Article 2417520. https://doi.org/10.1002/adma.202417520

Chen, Y., Liu, S., Zhang, H., & Wang, J. (2025). Emerging trends in AI-integrated optical biosensors for point-of-care diagnostics: Current status and future prospects. *Chemical Communications, 61*. https://doi.org/10.1039/D5CC04899K

Díaz-Fernández, A. (2025). Aptamer-based biosensors for point-of-care diagnostics. *Biosensors, 16*(1), Article 11. https://doi.org/10.3390/bios16010011

Han, G.-R., Goncharov, A., Eryilmaz, M., Joung, H.-A., Ghosh, R., Yim, G., Chang, N., Kim, M., Ngo, K., Veszpremi, M., Liao, K., Garner, O. B., Di Carlo, D., & Ozcan, A. (2025). Machine learning in point-of-care testing: Innovations, challenges, and opportunities. *Nature Communications, 16*, Article 3165. https://doi.org/10.1038/s41467-025-58527-6

Kaur, H., Siwal, S. S., & Thakur, V. K. (2025). Role of machine-learning-assisted biosensors in point-of-care testing for clinical decisions. *ACS Sensors, 9*(11). https://doi.org/10.1021/acssensors.4c01582

Zhang, X., Xu, T., & Jin, X. (2026). Microinterventional in-sensor computing system for real-time metabolic health assessment. *Nature Communications, 17*. https://doi.org/10.1038/s41467-026-72520-7