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The successes and challenges in the development of sensors for medical diagnostics

 Sabine Szunerits ^a and Xueji Zhang^b

Biosensors are analytical devices that contain a biological recognition element to capture the analytes and a transducer to convert the recognition interactions to a measurable signal. Biological recognition elements could be nucleic acids (DNA and RNA), aptamers, peptides, enzymes, antibodies, and microorganisms. The biochemical properties of biorecognition elements make biosensors highly sensitive and highly selective for the analyte of detection with minimum interference in the presence of other biologically active molecules or species in the tested samples. The transducer converts the biorecognition event into a measurable signal that may be electrochemical (amperometry, potentiometry, and impedimetry), optical (*e.g.* plasmonics, luminescence and colorimetry), piezoelectric, micromechanical *etc.* Biosensors provide many attractive advantages including high sensitivity and specificity, rapid response, relatively compact size with user-friendly and cost-effective operation, allowing time analysis. Therefore, biosensors have a very promising future in many application fields, including early diagnostics of diseases and health monitoring.

In the past decade, the development of new biosensors for medical diagnostics has increased significantly, especially since the start of the SARS-CoV-2 pandemic, when a surge in research in the field of medical diagnostics was observed. We are experiencing a clear shift from the development of conventional, laboratory-based testing systems towards tests that can be used directly at the point of care (POC). This trend is further driven by the pressure on healthcare systems as well as the demand for efficient healthcare provision in emerging economies, even further accelerated by expanding population size. It is worth mentioning here that while smartphones have become a part of our daily life with more compact forms being available each year, their conjunction with add-on devices has shown a great capacity for data collection, analysis, display, and transmission, making them popular in POC diagnostics.

Integration of biosensors with various clinical diagnostic applications is especially valuable in the early diagnosis of diseases such as cancers. In this method, the biosensor aims at the detection of various biomarkers, which are biological molecules found in blood, other body fluids, or tissues that are a sign of a normal or abnormal process. The significance of using biosensors to detect disease biomarkers lies in two main aspects: one is early disease detection and monitoring disease

progression, and the other is the evaluation of the value of certain biological molecules to see whether they can serve as an effective biomarker. However, for most of the known biomarkers, the current progress of biosensor technology has yet to show sufficient sensitivity and specificity for translation of them into routine clinical use or for treatment monitoring.

Biosensors for rapid diagnostics such as lateral flow immunoassays (LFAs), techniques designed to miniaturize nucleic acid amplification such as PCR and LAMP, and cartridge-based sensors, are one of the sensor platforms currently at the forefront of research interests as they provide strategies for on-site detection. It is important to note that similar sensor concepts can be applied for food safety and environmental monitoring, with each application area having its own set of demands and requirements.

Advancements in nanotechnology have largely contributed to addressing different challenges in using biosensors for clinical diagnostics. A great variety of nanomaterials have been incorporated as transducers to increase the powerful potential of biosensors. Versatile nanomaterials can not only generate various signal modes but also help with signal amplification, thus their integration into sensing devices has considerably improved their detection limits. Additionally, nanomaterials' resistance against interfering molecules

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has resulted in improved anti-fouling characteristics of the resulting sensors, further enhancing their analytical performance. It is clear that the nanomaterials-driven development of biosensors will continue to be important in the next decade.

Additionally, bionanotechnological advancements have fed back positively into sensors and diagnostic platforms, thanks to improved surface chemistry and read-out strategies. The possibility of antibodies being replaced by nanobodies and other engineered high-affinity bioreceptors can potentially further increase sensors' performance. Finally, the gene editing property of CRISPR has found various applications in the diagnostics of cancer, neurodegenerative disorders, genetic diseases, blindness, *etc.*

Wearable as skin-integrated biosensors is another area of increasing research activities, which compared with common biosensors possess several advantages such as flexibility, lightness and portability. Nowadays, wearable biosensors are developing rapidly by integrating noninvasive sample collection technology, including microneedle-based sampling and microfluidic-based sweat collection, advanced flexible material technology, data processing chips and wireless communication technology.

Despite the excitement around many emerging sensing and diagnostic technologies, there are still several

problems to solve; these include the ability to sense low analyte concentrations in complex and diverse matrices in a time- and cost-efficient manner. While the properties of CRISPR/Cas make it a powerful diagnostic tool with the potential for excellent accuracy, the technology only sees a handful of point-of-care applications. Despite the suitability of carbon-based nanomaterials like carbon nanotubes and graphene for sensing purposes, their commercialization in transducers remains limited. Co-funding of developments around the commercialization of graphene-enabled products is an important initiative by the EU-based Graphene Flagship and leading European industries to catalyze the updating of such sensors in the diagnostic field.

We hope that you enjoyed reading through this summary of state-of-the-art developments in the biosensors field and associated problems. We invite you to read through the papers that offer solutions to the above mentioned and many other challenges on the pages of **Sensors & Diagnostics**, a new open access addition to the Royal Society of Chemistry (RSC) journal portfolio celebrating its first anniversary. Please follow us on [Twitter](#) or sign up for our **e-alerts** to stay up-to-date with the publications in the journal.

It is worth mentioning that the RSC covers the costs of publishing in the journal until mid-2024 so you are most

welcome to submit your own work to us and we will publish it free of charge. We are looking forward to receiving your work on the development of new sensors and diagnostic devices.

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