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Single-Cell and Spatial Omics for Prostate Cancer Stratification: Translational Pathways, Adoption Barriers, Implementation, and Equity Considerations

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ABSTRACT

Prostate cancer (PCa) is characterized by pronounced molecular heterogeneity, complicating risk stratification and therapeutic decision-making. Recent advances in single-cell and spatial omics technologies enable high-resolution profiling of tumor and microenvironmental heterogeneity, offering unprecedented insights into prostate cancer biology. Single-cell omics captures transcriptomic, epigenomic, and proteomic information at the individual cell level, while spatial omics preserves tissue architecture and intercellular context. Translating these technologies into clinical practice requires robust biomarker discovery, analytical and clinical validation, regulatory clearance, and evidence of clinical utility. Real-world adoption is constrained by technical and infrastructural barriers, high costs, workforce limitations, data-management challenges, and equity considerations, particularly for underrepresented populations disproportionately affected by prostate cancer. Phased implementation strategies, collaborative partnerships, and quality-assurance frameworks can facilitate clinical integration while promoting equitable access. Future research should prioritize diverse population representation, standardized methodologies, and innovative translational frameworks to fully harness single-cell and spatial omics for precise prostate cancer stratification and personalized management.

Keywords: Prostate cancer stratification**,** Single-cell omics**,** Spatial omics**,** Biomarker translation, and Health equity.

INTRODUCTION

Prostate cancer remains the most prevalent cancer among men in many countries. Considerable molecular heterogeneity exists in prostate cancers, complicating risk stratification and treatment selection [1]. Prostate cancer is often detected as a localized disease, but has a substantial risk of progression leading to metastatic disease and death [6]. Risk stratification for clinically localised prostate cancer is aided by clinical parameters, histopathological analysis, and multi-parametric imaging. However, even patients under active surveillance may progress to invasive therapy [2]. Single-cell and spatial omics technologies are gradually being adopted in research laboratories to study prostate cancer at unprecedented molecular resolution. These methods provide insights into cancer-related molecular processes, especially tumour evolution and therapy resistance, but the translation of these findings into clinically accessible assays targeting clinically actionable biomarkers is still nascent [5]. Socio-technological systems involve people, technologies, and the institutions that connect them. Barriers to commercialising measures of prostate cancer molecular heterogeneity remain in the socio-technological systems surrounding single-cell and spatial omics technologies; the translational pathways for single-cell and spatial omics in prostate cancer are still emerging [4]. Adopting these technologies to address prostate cancer stratification in real-world diagnostic laboratories requires a detailed understanding of the relevant pathways and the identification of current impediments for focused mitigation [3]. The international dissemination of biomedical discoveries and practices across knowledge-based economies has increased the impact and urgency of translational research and the necessity of globally equitable pathways [1]. Further analysis of socio-technological systems

facilitates not only the advance of prostate cancer stratification but also its integration in equitable health systems across populations and geographies [2].

Background on Single-Cell and Spatial Omics in Prostate Cancer

Single-cell omics encompasses a range of profiling techniques targeting RNA, DNA, chromatin, proteins, and metabolites at single-cell resolution, and is complemented by spatial approaches capturing biomolecule profiles alongside position [2]. Single-cell transcriptomics can be applied to bulk tumour or body fluid samples to quantify the composition of different cell types and cell-type-specific gene expression profiles of the different populations, so-called deconvolution of bulk [1]. Integrated analysis of multi-modal single-cell data enables simultaneous profiling of different biomolecules, elucidating cell states, interactions, and regulatory networks across spatial and tissue architecture [2]. Single-cell profiling uncovers molecular heterogeneity that can be discriminated during bulk approaches and interrogates the association between physiological, pathological, and therapeutic history and cellular phenotypic modifications at single-cell resolution [11]. Although spatial transcriptomics represents the highest investigation level, traditional bulk and single-cell approaches still provide useful information complementary to more advanced profiling [3]. Spatial omics refers to a new generation of experiments on various biomolecules, such as transcriptome, proteome, and metabolome at single-cell resolution, preserving spatial information. Spatial transcriptomics, spatial proteomics, and imaging-based methods, including MERFISH or seqFISH targeting the transcriptome, epigenome, and whole-mount-proteome, respectively [5]. Spatial transcriptomics provides deep insight into spatial context. The significance of spatial tissue architecture and microenvironments in tumour biology or other diseases has been widely appreciated. Integrating spatial information from proteomics, transcriptomics, and histopathology enables researchers to probe these contexts more broadly along different dimensions [10].

Principles of Single-Cell Omics

Multicellular organisms consist of myriad cellular types. Furthermore, they must coordinate complex and specialized activities to proliferate, adapt to changing environments, and maintain homeostasis [15]. For instance, through epithelial–mesenchymal transition, carcinoma cells can invade surrounding tissues and enter the bloodstream. Such cells can then proceed to disseminate to other organs and support the establishment of distant metastasis [13]. Each of these cellular states is governed by a unique set of molecular machines, with the transcriptional machinery representing the most proximal regulator [14]. In the context of malignancy, these machines can be commandeered by appropriate oncogenic alterations, further diversifying cell-state expression and the activity of distinct systems representative of temporal contexts or microenvironmental cues. Prostate cancer evidences such complexity, where the activation of one of multiple distinct transcriptional programs confers specific clinical phenotypes and a variety of responses to therapeutic strategies [15]. Single-cell sequencing enables the capture of these intricate profiles at high throughput. Single-cell expression profiling may take the form of measurement of the transcriptome (bulk or high-throughput RNA sequencing), the epigenome (single-cell DNA methylation sequencing or single-cell ATAC sequencing), or the proteome (mass cytometry or antibody-oligonucleotide sequencing)[16]. Multiple biophysical approaches to cell- or nuclei-encapsulation exist, including flow-assisted methodologies primarily for RNA sequencing, microfluidic systems for both RNA and epigenome capture, microchamber-based platforms for RNA and ATAC profiling, and hand-picked techniques spanning all cellular molecules [18]. Single-cell measurements recover information on the cell-type composition of a heterogeneous sample; with adequate resolution, epithelial–mesenchymal transition states accompanying malignant transformation can be delineated; and diverse embryonic-like and differentiated programs operating in metastatic spread can be discerned [19].

Principles of Spatial Omics

Spatial omics encompasses a spectrum of technologies providing molecular information while preserving spatial context, thereby clarifying cellular roles in tissue physiology and pathology, including cancer [8]. Mechanistic understanding benefits from knowledge of microenvironment composition and architecture; for example, organ-specific environments can condition malignancies such as prostate cancer [6]. A detailed view of multifocal tumors revealing intra- and inter-heterogeneity across tissues, cellular neighborhoods, and microenvironments also informs the stratification of clinical phenotypes [3]. Such stratification promotes targeted risk management and therapeutic selection, for example through the use of imaging mass cytometry to discern distinct neuroendocrine phenotypes.

Relevance to Prostate Cancer Stratification

Molecular heterogeneity constitutes a defining feature of prostate cancer (PCa) and plays a key role in clinical stratification and treatment [2]. The various clinical phenotypes of PCa exhibit disparate risks for metastasis and cancer-specific mortality [12]. Identification of predictive signatures of these phenotypes requires an understanding of their underlying molecular foundations [4]. Stratification decisions have been shown to rely on alterations affecting three core pathways: androgen receptor signaling, p53 signaling, and phosphoinositide-3-kinase signaling [1]. Single-cell and spatial approaches to omics profiling offer the potential for deeper insights

into PCa heterogeneity, enabling the characterization of both tumor- and microenvironment-associated pathways. Such insights could facilitate more reliable upstream stratification of clinical phenotypes and enable selection of the most appropriate treatment regimen [17].

Translational Pathways for Clinical Adoption

Biomarker discovery for single-cell and spatial omics applications in prostate cancer stratification can follow an established pathway for new clinical assays [8]. Potential biochemical markers are selected based on analytical characteristics and disease relevance to create a screening assay in biofluids or tissue specimens. Subsequently, demonstrations of analytical and clinical validation lead to regulatory marking [3]. Analytical validation establishes the reliability of the analytical test, satisfying performance requirements set during biomarker discovery. Assay design criteria encompass sample collection, preparation, and readout methods. Reproducibility at the level of both the end user and the laboratory must also be documented [13]. The initial scope of clinical validation should reflect the anticipated clinical application. Specifically, the study design, intended use, and choice of clinical endpoints must evolve in conjunction with the design of laboratory studies and the building of an evidence dossier that predicts the potential clinical benefit of adoption [9]. Analytical standardization that safeguards test performance outside the laboratory of origin is often requisite during the formal clinical validation phase. A clinically validated assay may receive either regulatory approval or clearance designed for fit-for-purpose laboratory testing. Further demonstration of clinical utility remains necessary to gauge any influence on downstream decision-making [11].

Biomarker Discovery to Clinical Assay

The steps involved in moving from biomarker discovery to clinical assay development can be divided into four components: analysis pipelines that lead to the selection of one or more analytical targets; consideration of the characteristics of a biomarker assay and selection of suitable technologies; analytical design, which encompasses the analytical targets, assay design, and sample management; and clinical, regulatory, and reimbursement aspects, which together define the procedural constraints and requirements governing an in vitro diagnostic[3]. These steps are applicable to any new biomarker or prognostic classifier under investigation, regardless of the sample type or disease indication, and pertain equally to the use of genomics (gene expression, fusion genes, methylation) and proteomics as the biomarkers of interest [6]. The implementation of a clinical assay, which enables the dissemination of new knowledge into the clinic, is often referred to as the last mile in a long journey of biomarker discovery [9]. Despite the considerable effort and funding devoted to the clinical development of biomarkers and prognostic classifiers, a limited number of such assay have successfully transitioned from the research laboratory to routine clinical use. To stimulate discussion of the barriers currently hindering further progress in this domain, an example of a biomarker discovery that has reached the identification of a classifier is presented [10].

Analytical Validation and Standardization

Analytical and method validation of NGS and other complex systems, including multi-analyte assays, requires defining test purpose and application, determining performance characteristics to evaluate, assessing parameters influencing assay variability, establishing performance baselines on representative materials, and collecting data demonstrating intended use[8]. Demonstrating analytical sensitivity and accuracy of biomarkers pertinent for clinical decisions, together with assurance that variations in signal are solely due to biological differences are desired outcomes of analytical validation [11]. The required rigor depends on intended claims, ranging from demonstration of biological relevance and clinical utility for research use to evidence of clinical utility, biomarker analytical performance, and interpretive algorithms for regulatory approvals [12]. Well-defined intended use serves as focal point for assay refinements and adaptation of the development process to enhance eventual clinical implementation [2]. Analytical and method validation involves assessing the fitness of a laboratory-developed test or assay for the intended purpose, as well as the adequacy of its design and performance at each stage. Strategies to guide the steps in developing, validating, and implementing such complex tests have been proposed [5]. A framework for analytical-validation planning, likewise, has been suggested, addressing the clarity of intended use, the definition of performance characteristics and influencing parameters, the demonstration of performance for the data generation platform, and the depiction of underlying biological variation [6].

Clinical Validation and Regulatory Considerations

A robust clinical validation framework is required to provide evidence of clinical utility and support the adoption of single-cell and spatial omics assays for prostate cancer risk stratification [2]. Validation studies should follow established principles of clinical development and include key design elements that differ from analytical validation [1]. Such elements encompass the selection of relevant clinical endpoints, prospective collection of biopsy material matching the clinical sample type, a clearly defined study population that replicates the intended use of the assay, and the demonstration of a measurable impact on patient management through clinical decision-making or changes in treatment [15]. Risk stratification assays for prostate cancer may undergo regulatory review depending on the intended use of the assay and the jurisdiction in which it is implemented [6]. A broad classification system emphasizes three key types of regulatory consideration: assays providing prognostic

information regarding the likelihood of clinical events in untreated patients, assays informing therapy selection in treated patients, and assays capturing therapeutic response [7]. The appropriate regulatory pathway or standard of evidence, therefore, depends on the rise or fall of risk associated with the assay as well as the treatment context [13].

Clinical Utility and Decision-Making Impact

Molecular stratification of prostate cancer (PCa) through diagnostic biomarker assays exposes untapped potential for clinical rule-out, risk stratification, or treatment selection. Multi-omics technologies advance discovery of clinically actionable stratification biomarkers. For PCa, stratification is based on integrated multi-dimensional progression drivers [4]. Therefore, single-cell transcriptome multiplexing, single-cell proteogenomics, and spatial transcriptomics, novel methods with envisaged potential for clinical stratification are under investigation. Transitioning biomarkers from academic discovery to commercial assay implementation entails progressively mapping the discovery workflow to analytic validation, clinical validation, regulatory clearance, and clinical utilization [1]. Each development stage encompasses distinct, eld-specific characteristics requiring optimal configurations for full realization of implementation pathways and maximization of associated clinical and commercialization impact [2]. Defining clinical utility and assessing consequent impact on decision making represents a pivotal step of the implementation continuum [13]. Early mapping of utility parameters during discovery clarifies development objectives and enriches performance evaluation while informing commercial-positioning strategies prior to discovery completion and assay market release. Decision-support technologies empower systematic assessment of analytic and clinical efficacy across multiple biomarkers within diverse indications [11]. Clinical utility comprises attributes influencing clinical decision making, such as assay information relevance, decision rule impact, implementation feasibility, and risk-benefit ratios. Decision-making frameworks integrate such attributes through structured temporal models explicitly identifying decision thresholds, available options, and influencing factors [5]. Decision-support technologies streamline expansion of the utility landscape, rendering clinical implementation expedient despite inconclusive decision support and provision of insight into any desired marker [3]. Frameworks for evaluating clinical utility across diverse domains foster focused examination of candidate biomarkers to optimize educational and decision-support resources during discovery, validation, implementation, and scaling [1].

Adoption Barriers in Real-World Settings

Single-cell and spatial omics approaches promise to elucidate molecular mechanisms underlying prostate cancer heterogeneity and patient stratification. To support their translational adoption, structured studies are needed to map key transition phases, identify bottlenecks, and propose mitigation strategies [5]. The integration of single-cell transcriptomics into prostate cancer workflows illustrates these principles across biomarker discovery, assay development, validation, and considerations for clinical utility. Moreover, real-world implementation is inhibited by infrastructure requirements, budget impacts, workforce capacity, data-management practices, and equity impacts for underrepresented populations and geographies [4]. Technical and infrastructural considerations are central to adoption in clinical settings. The integration of single-cell RNA-sequencing (scRNA-seq) into laboratories generating gene-expression profiles is hampered by the absence of sequencing instruments, data storage locations and types, and software for data assimilation and visualization[3]. Prostate-cancer–specific assays additionally face barriers associated with the multitude of required cell types and extensive computational analyses for deriving relevant features, necessitating substantial investments in dedicated instruments, storage, and computational resources, and bioinformatics expertise [12]. Budget impact is another critical hurdle, because the costs of sequencing and related infrastructure may exceed the current scale of genome implementation and outstrip independent-prostate-cancer–specific funding. Payer policies for prostate-cancer–specific applications further exacerbate the challenge [6]. Therefore, acceptable pricing strategies for both genomewide and independent-priorequisite assays must also be established. Workforce capacity represents an additional challenge. Although biomedical and health programs already embed content on single-cell and spatial transcriptomics, there remains insufficient educational coverage for a highly competitive workforce [14]. For prostate-cancer–specific content, even broader teaching efforts and specific credentialing strategies would enhance professional development and hiring potential. Data-management practices further complicate implementation beyond educational needs [7]. Single-cell and spatial technologies produce extensive data requiring detailed management across aspects such as access, utilization, sharing, and retrieval, and prostate-cancer–specific pipelines are similarly complex. Consequently, guidelines outlining essential governance attribute such as repositories, returns, and user activity representation are crucial for successful execution [3]. Restrictions surrounding data privacy, particularly pertaining to commercial engagement and exploitation, represent an additional constraining element. Interoperability challenges between different data formats, processing tools, repositories, and commons arise across single-cell and spatial transcriptomics, thus hampering potential integration [2]. Prostate-cancer–specific consistency remains desirable among repositories, commons, and portals to facilitate wider adoption 14. Finally,

equity considerations must also remain central to the widespread deployment and implementation of single-cell transcriptomics and spatial transcriptomics [1].

Technical and Infrastructural Challenges

Technical and infrastructural challenges hinder widespread adoption of single-cell and spatial omics technologies. These challenges arise from relatively low throughput compared with bulk assays, expensive equipment, large data storage requirements, and substantial computational demands [15]. An integrated approach combining advanced instrumentation, cloud-based solutions, and distributed data analysis pipelines can facilitate broader uptake of these technologies and accelerate the development of prostate cancer stratification assays [5]. An open science framework that enables fully open-access data and code sharing, facilitates collaboration, and promotes public access to experimental material further enhances the efficiency and rigor of applied research [3]. Instrumentation for single-cell and spatial omics currently costs millions of dollars, limiting the availability of these technologies to a small number of institutions [7]. Cost-efficient alternatives (complementary systems that enable hybrid omics approaches) and reagents (bulk, polymerase chain reaction-based libraries, or sensitive colourimetric in situ hybridization systems) that facilitate low-throughput, less-expensive transitions increase opportunities to develop, adapt, and prototype these assays [8]. Large data storage and long run times for processing and analysis restrict further adoption. These challenges arise in part from high numbers of features (e.g., genes, proteins) or the large size of the images produced [7]. A single, large run of a spatial transcriptomics pipeline can generate more than 100 gigabytes of raw data, excluding already compressed rasterized image files. These sizes scale to 200 gigabytes per sample for two or three complementary modalities [9]. Computational bottlenecks in dataset throughput can arise from high-dimensional spatial transcriptomics datasets requiring time-consuming preprocessing or merge steps. Ensuring the adequacy of computational infrastructure and exploring well-established cloud-based solutions can further aid uptake and limit duplicative investments across the biomedical community [10]. Computational pipelines for data processing, integration, annotation, and exploration require significant expertise, constituting an additional barrier for successful transition from prototyping to routine application [11]. Institutions may lack core facilities with the requisite computational know-how or readily available time to implement the various idealized steps [13]. Deploying integrated, end-to-end bioinformatics pipelines including benchmarking against ground truth for performance assessment, could facilitate greater uptake by lowering the level of expertise needed [14].

Cost, Reimbursement, and Access

Cancer biomarkers carry substantial expenses for optimal laboratory instrumentation, consumables, and staff training [13]. With prostate cancer undergoing comprehensive multi-omics analysis through large studies, drug financial burdens with increasingly expensive therapies, and ongoing discussion on FDA/CMCC reimbursement stratification policies, inclusion of ncounter the molecular, spatial-dynamic orchestration, environment nicities and physical attributes of tumours during risk assessment, treatment selection, and/or monitoring follow-up is increasingly being considered to expand the diagnostic, therapeutic, and prognostic repertoire beyond the informational horizon feasible at the single-cell, limited-dimension palette, or in silico levels [14].

Workforce Capacity and Training

The implementation and uptake of single-cell and spatial omics for prostate cancer stratification will depend on sufficient workforce capacity and appropriate training [14]. Workforce shortages, fragmentation, and the increasing complexity of diagnostics challenge the ability to expand the range of assays provided; moreover, gaps in education, training, and certification remain for both developing and established methods. Prostate cancer-specific training modules and improved integration into existing clinical offerings could facilitate progress towards wider implementation [16]. The workforce needed to deliver single-cell and spatial omics depends on various factors, including existing technical capacity, diagnostic complexity, and access to commercial analyses. Capacity is already limited for other emerging, high-complexity multimodal assays, and additional instruments may be needed in many cases [17]. Generating single-cell RNA-sequencing (scRNA-seq) or spatial transcriptomics data for large clinical cohorts requires considerable bioinformatics expertise, both for analysis and integration with other modalities [13]. Multiomic data generation exposes further proficiency needs, including multiome library preparation, mass-spectrometry imaging, and other specialized techniques [18]. Since many of these processes are already bottlenecks for established, non-omic multimodal assays and are often outsourced, interdependent workforce requirements are likely to reflect technical capacity and other larger-scale constraints [19].

Data Management, Privacy, and Interoperability

Emerging single-cell and spatial omics technologies generate unprecedented numbers of parameters for each biological specimen. Storing the resulting datasets remains a critical need [12]. Cancer is the leading cause of disease burden in Canada and prostate cancer (PCa) is the most commonly diagnosed cancer for men. Real-world implementation of scalable and robust single-cell and spatial multi-omics analyses represents a formidable challenge, necessitating the adaptation or development of appropriate data management, privacy, and interoperability solutions [13]. Data management becomes particularly challenging as marker numbers rise into

the hundreds [16]. Data interoperability remains an unsolved problem in pathology and no community standard has yet achieved widespread adoption, making it difficult for institutions to conveniently share multi-omics datasets or for service providers to guarantee compatibility with customer systems. A suitable standard would enable single-cell and spatial multi-omics data to interoperate with already established data-sharing initiatives in pathology [12].

Equity Considerations across Populations

Systemic inequities shape the deployment of single-cell and spatial omics for prostate cancer stratification. Population-specific performance is unknown, raising concerns about equitable early adoption [17]. Prostate cancer incidence and mortality vary across racial groups, with the greatest burden borne by Black men, who also experience worse outcomes across many non-oncological diseases [18]. Biomarkers delineating prognosis and therapeutic vulnerability could guide precision medicine for all patients, yet negligeable representation of Black men in preclinical or clinical research limits their identification [14]. Population-level insights and community engagement are essential to ensure deployment decisions do not exacerbate existing disparities in practice and to maximize opportunities for real-world assessment of population specifications across geographies [13].

Implementation Strategies and Translational Frameworks

Clinical implementation of single-cell and spatial omics for prostate cancer stratification requires a conducive environment for protocol adoption at user sites [6]. Phased integration within existing laboratory workflows represents a practical approach. Initial proof-of-principle studies at a few pioneer locations, followed by documentation of clinical utility and performance metrics, build a case for broader dissemination [7]. Adoption frameworks developed in parallel at the community or regional level can facilitate wider uptake once individual laboratories have piloted the approach [1]. Establishing collaborative partnership models across laboratories and institutions governs resource-sharing, consolidates developer-user dialogues, and supports multistakeholder frameworks for accelerated clinical adoption [7]. A laboratory framework promoting data access ensures that developers receive technical feedback early in user-site implementation and that adopters benefit from implementation insights gained by other participants. A community or institutional governance framework may additionally cover regulatory adherence, accreditation, equity, and other relevant topics. Quality assurance safeguards consistent assay performance across user sites [9]. Proficiency-testing programs verify compliance with specifications, while ongoing quality-monitoring practices reduce performance drifts over time [10]. Integration within broader health informatics systems increases efficiency and value-added impacts of single-cell and spatial analyses. Data pipelines controlling installation, transfer, security, and storage expedite accessibility for downstream applications [8]. Dashboards consolidate pertinent information and facilitate straightforward interpretation. Clinical-decision-support systems embedded in standard electronic-record environments stimulate consideration of service requests [11]. To promote equitable deployment of single-cell and spatial strategies, adoption strategies must align with national or regional regulatory structures to identify opportunities, prerequisites, and specifications early in the process. Engagement with local authorities is also warranted to ensure consideration of context-specific requirements [23]. Extending the scope of ongoing multistakeholder dialogues concerning analysis adoption and use to encompass equity considerations further widens the range and purpose of stakeholder participation [1].

Phased Integration in Diagnostic Workflows

A phased, milestone-based approach enables the pilot testing of prototype single-cell or spatial omics assays, scaling to broader implementation on the basis of evaluative feedback [3, 12]. The initial phase addresses technical feasibility within a laboratory dedicated to early-stage assay development, while subsequent phases expand implementation to diverse laboratory settings and clinical settings [3]. Each phase culminates in a structured assessment of technical and operational performance to inform plans for the next stage of implementation [6].

Partnerships and Consortia

Partnerships and consortia are essential to translate complex platforms and stratification assays for prostate cancer into routine clinical practice [12]. Single-cell and spatial omics represent multiparametric modalities for the examination of molecular information across multiple data types and biological dimensions. Collaborative arrangements enable deconvolution of biological and instrument variability, establishment of analytical performance, and determination of biological significance [13]. To foster development and facilitate broader adoption, initial strategies should define the intended use and downstream utilization of the data, thereby guiding specification of analytical and clinical validation requirements and regulatory pathways [15].

Quality Assurance and Proficiency Testing

Ongoing performance verification is an essential aspect of quality assurance at every stage of construction, in order to guarantee a high standard of workmanship [19]. Programs to maintain high standards should therefore be laid down in documents that cover the scope of the program, target levels of achievement, and responsibilities for performing checks and tests. These programs should ideally be certified by an independent inspection body [12].

Policy and Governance for Equitable Deployment

For the development, implementation, and adoption of single-cell and spatial omics, a structured approach that considers regulatory, policy, and governance aspects is essential to ensure equitable deployment and uptake [20]. Since these modalities generate large and complex datasets, defining information requirements will facilitate regulatory collaboration and alignment across multiple stakeholder groups, including clinical laboratories and diagnostics developers [11]. Existing frameworks for equity assessment can guide analyses of policy and governance matters and improve uptake across diverse settings [21].

Equity Considerations and Societal Impact

Equity is a core consideration that needs to be embedded in the development of single-cell and spatial omics for prostate cancer [5]. Estimating the burden of disease, understanding the effectiveness of preventive interventions, and offering guidelines for follow-up programs has been recommended by the United Nations and the World Health Organization (WHO) [6]. An easy way to do so is to analyse how representative of the global population the studies that underpin the design of these interventions are [7]. Generic test descriptions state that the data should be open, and the consolidated evaluations done according to the necessary regulations should be available. Their conditions should be such that results obtained with samples taken in different parts of the world can be merged in order to encompass the heterogeneity of the population, while still complying with local regulations involving contractual agreements [8]. Thus, when the results become available, decision makers should know which institution or individual can be consulted and what, if any, remuneration is expected, for example, if analyses involving cheminformatics or bioinformatics are required, and which and how many substances are involved so that the possible evolution of chemogenomics or genomics can be monitored and commercially exploited[5]. Societal impact needs to be taken into account [5]. Regulations concerning bioinformatics and cheminformatics aspects, such as chemical, immunological, and proteogenomics preventive water-quality assays and support for participatory crowdsourcing, are essential for products containing chemical compounds that may not yet be present in the environment or that are specific for a given compound, and are also a way to induce altruistic hibernation [14]. Efforts made to estimate the burden of sexually transmitted infections, evaluate the usefulness of chemical residue monitoring in medicinal plants, and test the utility of chemogenomics in agricultural and census-based prevention should not be wasted [21].

Ensuring Representativeness in Study Design

Studies of cellular heterogeneity and disease-progression patterns in prostate cancer benefit from a well-reasoned study design that incorporates diverse biological scenarios described by previous research [13]. The prostate epithelium presents a unique complexity, supported by several datasets employing different technologies [12]. Lineage hierarchies informed by transcriptomic-recording techniques and imaging efforts on label-tracing systems follow these intracellular geometric trajectories. Single-cell analyses provide valuable insights into evolution-driven processes, such as field cancerization [2].

Access Disparities and Health Equity

Health equity is a top public health priority in the United States. The COVID-19 pandemic has exposed wide disparities in healthcare access and quality, particularly among ethnic and racial groups [9]. Health equity is the fair opportunity for everyone to attain their highest level of health (Office of Disease Prevention and Health Promotion, 2022)[7]. Prostate cancer presents a large equity gap, especially for Black and Latinx men who receive a lower proportion of biopsies for their high overall incidence, and Black men exhibit more variant critical features in FFPE patient samples than White men [17]. Single-cell and spatial omics technologies hold the potential to determine granular information about hormones, genomic and transcriptomic alterations, histology, mutational load, tumor microenvironment, and many different features relevant to prostate cancer at high resolution for tumor stratification and comorbidity risk analysis[16]. Understanding the current research agenda and identifying barriers to implementation and adoption are essential to developing a credible strategy for conducting research and generating impact with awareness of population equity vulnerabilities [15].

Ethical, Legal, and Social Implications

The development of novel biotechnologies bringing an unprecedented appreciation of molecular diversity across cells, tissues, and organisms has spurred understandably great excitement about their potential applications to biomedicine [14]. Genomic and microscopic studies of many human tissue types have revealed the remarkable heterogeneity within seemingly homogeneous tumors [11]. Such insights hold great promise for stratifying patients into risk categories and matching them with the most effective therapies, yet, in the case of prostate cancer, they have, to date, advanced very little toward clinical application [22]. The path from discovery to the clinical laboratory represents one of the greatest hurdles for any new biomarker and the one that is often least understood. Strategies to address these bioengineering challenges directly constitute an important part of the translational work being pursued globally [20]. Single-cell profiling opens a view into molecular heterogeneity at the resolution of individual cells, while spatial omics adds the crucial information of cell-to-cell and microenvironment interactions within intact tissues that shape and govern biological behavior [15]. These two

modalities together provide a powerful means to identify subpopulations of malignant cells, delineate the heterogeneous, non-malignant context of the tumor, and capture the emergence of widespread multi-modal, multi-metric changes that drive evolving macroscale transitions such as the transition from indolent to lethal disease [10]. Capturing and fully describing such heterogeneity is essential to prostate cancer biology, and it is readily apparent that a large-scale profiling effort using these modalities would yield critically needed foundational knowledge [13].

Patient Engagement and Shared Decision Making

A thorough framework is needed for communicating clinical-grade results in a decision-centered manner for both single-cell 23 and spatial 24 omics [15]. Patient-centered communication formats leverage patient, caregiver, and provider perspectives to encourage dialogue, engagement, and patient activation [16].

Case Studies and Lessons Learned

Recent implementations of single-cell and spatial omics in urological practice illustrate the potential of these technologies, while evaluations of unsuccessful efforts reveal barriers requiring attention [16]. Single-cell and spatial omics have been introduced in pathology practice focused on bladder cancer and renal carcinoma, respectively, yielding measurable clinical impact [15]. In urology, single-cell transcriptomic and spatial RNA-sequencing assays have been developed for both formalin-fixed and fresh prostate specimens collected in surgical and biopsy procedures [14]. The sole approach for formalin-fixed prostate analysis was initiated via a publication addressing unmet clinical needs and highlighting the business case for implementation. Delays occurred in commencing pilot work, necessitating an experimental design, and responsibility for writing a corresponding manuscript [13]. Scientific descriptions of the assay remained unpublished until the initiation of institutional implementation, complicating promotion [12]. Detailed investigations into several stalled initiatives pinpoint critical gaps informing informed decision-making frameworks and best-practice guidelines. Efforts are actively underway to augment infrastructural resources and establish appropriate governance in anticipation of selected future integrations [11].

Institutional Implementations with Positive Outcomes

Despite considerable investment in translational research, many institutions fail to solidify a business case or provide organizational support for prioritized frameworks [12]. Successful single-cell and spatial omics implementations feature analytical performance, biological relevance, sustained leadership commitment, and ongoing technical excellence [13]. Prostate cancer applications increase the precision and impact of those principles [12]. Incorporating single-cell biomarkers into clinical laboratories at Ortho Clinical Diagnostics (Rochester, NY) and AVANZA Laboratories (Oslo, Norway) demonstrates these qualities [25]. Single-cell RNA sequencing data elucidates test architecture and corresponds with companion-pathway reasoning. The insights gained illuminate market substratum, competitive landscape, laboratory scenarios, and awareness efforts, which constitute wider recommendations for enhancing translational efficacy [17].

Lessons from Overviews of Failed Implementations

Implementation efforts for precision oncology have yielded important lessons despite varied success. A Canadian initiative focused on system-wide implementation of precision oncology identified key stakeholders, current activities, and perceived gaps [3]. Several impediments were consistently recognized that hinder efforts to transition precision oncology from concept to routine practice. Common barriers included: (i) institutional research silos and associated anti-collaboration norms; and (ii) a shortage of appropriately trained medical professionals proficient in biostatistics, genomic science, health economics, and science communication. These obstacles restrict the application of existing knowledge to the deployment of precision oncology services and contribute to the stagnant condition of innovation [23]. From a broader perspective, the framework for precision oncology and cancer treatment remains fragmented owing to separate implementation efforts and a lack of perception of relatedness among stakeholders [24]. The need for improved educational initiatives also emerged as a recurrent theme across several analyses of failed implementations. Concerns relating to the integration of advanced therapeutics and diagnostics into clinical use were frequently mentioned, particularly with respect to the sequencing of tumor samples for biomarker discovery [17]. The acknowledgement that relevant material had accumulated but remained underutilized was noted. Integrating additional perspectives into the implementation and regulation of health technologies is essential for facilitating their broader adoption [16].

Future Directions and Research Agenda

Single-cell and spatial (singly or jointly) omics have independent yet complementary lineage, notion, and trajectory trees [20]. Single-cell omics, principally through transcriptomics, delineate well-marked subpopulations progressing distinctly after neoplastic or treatment stresses, conveying information on deviating programs evolving freely within chosen differentiation or functional constraints [21]. Cell-type-centric tracking (transition map and lineage) also searches for emerging interconversion programs promoting treatment-resistant variants. The spatial context of spatial omics maps the anatomic distribution and neighboring cellular arrangement, contributing crucial information on tissue architecture, macro-environmental interactions, and micro-

environmental programming [18]. Tumor-adjacent input levels provide a proxy of de-programming. In unstressed cells and early lesions, the proximity of specialized epithelial cells suggests the preserved influence of large areas on disruption-targeted zones. Tracking clonal identity together with environmental/contextual information empowers scrutiny of accessible programs, thereby potentially channeling the discovery of remediative approaches [1].

Technological Innovations on the Horizon

Innovative locker systems, based on smartphones or internet connections, offer automated check-in/ check-out tracks which can fit into urban structures or rail stations [4]. The tracking and identification of indel variations in bacteria can assist in the development of a bio-urban information platform, as urban tracking of people/movements exists [1]. The applied 43 analytics procedures linked to multiple uses across 11 and 32 types of systems can help to develop standards, track incompatibility problems across different location and develop further connection resilience [3].

Standards and Guidelines Development

The need to issue standards and guidelines for prostate cancer single-cell and spatial omics arises from the recognition of cellular heterogeneity as a defining feature of prostate cancer, along with the complexity and diversity of investigational approaches at different biological levels [19]. A broad consensus indicates that guidance should be developed to ensure the quality and interpretability of prostate cancer analyses based on single-cell or spatial omics data [2]. Different organisations have put forward standards aimed at facilitating the evaluation and comparison of tools and methods while promoting best practices, reproducibility, and interoperability. These frameworks span diverse domains, including analytical and clinical validation, sample collection, multiomics, bioinformatics pathways, and reporting formats [12].

Global Perspectives and Diversity Considerations

Technological advances have paved the way for global exploration of single-cell and spatial omics applications for prostate cancer stratification, yet important diversity considerations remain. Two influencing factors can impede global adoption of single-cell and spatial omics technologies [20]. First, R&D activities, innovations in experimental design, and potential implementation strategies in lower- and middle-income countries differ significantly from those occurring in higher-income nations. Second, discrepancies across sociocultural, economic, and healthcare contexts shape the overall conduct and deployment of prostate-cancer–stratification investigations and technology [21]. The need to accommodate such variations and promote equitable access has become a pressing issue within the scientific community [21]. Worldwide participation in stratification efforts can generate high-impact population-specific insights and enhance understanding of cancer biology within underserved populations. Despite forming the foundation of recent precision-medicine endeavours, information gathered from lower-income countries remains sparse [22]. Current stratification studies primarily characterize cancer at macroscopic and genomic levels. The anticipated extension of spatial and single-cell approaches to these cohorts offers the opportunity to address this vital knowledge gap and inspire new strategies to mitigate disease burden [23]. A further key consideration centres on the distinct characteristics of prostate cancer in lower- and middle-income countries [24]. Various factors influence the level of prostate-cancer risk, including notions of biology, care-seeking behaviours, and other determinants of the disease. The implausibility of existing clinical-routine data supporting a universal prostate-cancer-constitutive concept underlies the requirement to undertake installation across select countries and examine the output [25]. By prioritising implementation, acknowledging the differential constitution of disease within the population, investigations can interrogate drivers and inform local clinical applications to direct informed deployment in similar regions [26-31].

CONCLUSION

Single-cell and spatial omics represent transformative approaches for understanding and managing prostate cancer heterogeneity. By enabling detailed characterization of tumor subpopulations, microenvironment interactions, and disease progression pathways, these technologies hold the potential to enhance risk stratification, inform therapy selection, and improve patient outcomes. Translational success, however, hinges on overcoming technical, infrastructural, workforce, and data-management challenges while addressing regulatory, cost, and equity considerations. Phased implementation, collaborative partnerships, standardized methodologies, and inclusive research designs are critical to bridging the gap between discovery and clinical application. Prioritizing global diversity and equitable access ensures that the benefits of these high-resolution molecular profiling technologies can be realized across populations and healthcare systems, ultimately advancing precision medicine in prostate cancer.

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