ORTHOPAEDIC DEVICE INNOVATION IN SOUTH AFRICA: CASE STUDIES EXPLORING THE EFFECT OF CONTEXT ON KNOWLEDGE DEVELOPMENT AND EXCHANGE

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ABSTRACT

Orthopaedic devices comprise a significant portion of the medical devices that are imported into South Africa. Through case studies, we investigated the effect of contextual factors on knowledge development and exchange in the orthopaedic device innovation system, using the technological innovation systems framework. Our findings revealed that the drivers of knowledge development and exchange were inter-sectoral collaboration, availability of resources, affordability of available devices, creating legitimacy for devices, and the positive externalities of allied innovation systems. The main barriers identified were those that hindered inter-sectoral collaboration. The critical roles of the university and of healthcare actors were also highlighted. These findings may be used proactively to address problems in the innovation systems and to develop policy and institutional mechanisms that are aimed at building the domestic medical devices industry.

OPSOMMING

Ortopediese toestelle bestaan uit ’n aansienlike deel van ingevoerde mediese toestelle na Suid-Afrika. Deur gevallestudies ondersoek ons die effek van kontekstuele faktore op kennisontwikkeling en -uitruiling in die ortopediese toestelinnovasiestelsel deur die tegnologiese innovasiestelsels-raamwerk te gebruik. Ons bevindinge toon dat dryfvere van kennisontwikkeling en -uitruiling intersektorale samewerking, beskikbaarheid van hulpbronne, bekostigbaarheid van beskikbare toestelle, die skep van legitimiteit vir toestelle en die positiewe eksternaliteite van verwante innovasiestelsels was. Die belangrikste struikelblokke wat geïdentifiseer is, was dié wat intersektorale samewerking belemmer het. Die kritieke rolle van die universiteit en gesondheidsorgakteurs is ook uitgelig. Hierdie bevindinge kan gebruik word om proaktief uitdagings in die innovasiestelsels aan te spreek en om beleid en institusionele meganismes te ontwikkel wat daarop gemik is om die huishoudelike mediese toestelbedryf te bou.

1. INTRODUCTION

The South African medical device industry was recently surveyed by the South African Medical Research Council (SAMRC) to understand the size, characteristics, and dynamics of the medical devices industry in order to unpack local capabilities, expertise, and stakeholders across the medical devices value chain, identify gaps and barriers in the industry, and suggest possible solutions to overcome these barriers in building industry [1]. About 90% of all medical devices are imported [2], as South Africa has a relatively limited production capacity for medical devices [1]. The local manufacture and exporting of medical devices is largely low-tech, low-value products, classified as ‘other medical devices’, ‘consumables’, and ‘diagnostic imaging’ [1]. Local manufacturers tend to focus on the export market, and include substantial re-exports of internationally-produced medical devices [3].

Medical device development is collaborative in nature, with different sectors having distinct roles. The healthcare sector identifies patient needs, has access to patients and their data, and informs the suitability

of technologies; universities and science councils are platforms for research and development with advanced or specialised resources, instrumentation, and expertise; while industry focuses on the development, production, and commercialisation of technologies [3-5]. The process of discovery and development in medical research is iterative [6], and does not follow a linear path between sectors. Inter-sectoral collaboration enables knowledge transfer and the sharing of capital across sectors while ensuring that technologies match patient needs and ultimately reach the market.

The term 'orthopaedic medical device' refers to a part, implant, prosthetic, or orthotic used to address damage to the body's musculoskeletal system. These devices play a role in addressing injury-related disorders, one of four elements of South Africa's quadruple burden of disease [7]. The value of imported orthopaedic devices is quite substantial, accounting for about 65% of surgical imports into South Africa [2], which indicates a potentially limited supply by the domestic market. Using case studies, we investigated the orthopaedic devices innovation ecosystem, addressing knowledge development by local organisations, and exploring how domestic knowledge production addresses national needs. We conceptualised orthopaedic devices as a technological field, and applied the technological innovation system (TIS) framework to understand device development.

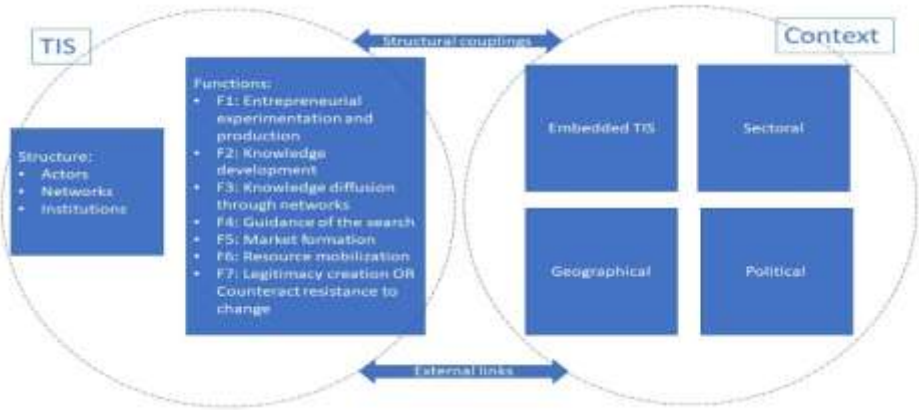

Figure 1: The structure and functions of the TIS, and its relationship to context

The TIS framework, illustrated in Figure 1, is divided into two parts: structure and functions. The structure comprises actors, networks, and institutions. Functions are core processes in a TIS that are complementary to the structure [8]. The functions of interest in this study are 'knowledge development', defined by Bergek *et al*. [9] as the act of learning and the activities in which learning takes place; and 'knowledge diffusion through networks', which describes the exchange of information within and between networks, extending to activities of learning by doing, using, and interacting [10, 11]. The way in which the TIS is linked to its context may present in different forms, including that of the embedded TIS, geographical, sectoral, and political nature [12]. The TIS interacts with the context in one of two ways: 'structural couplings' or 'external links'. Structural couplings are shared elements (actors, networks, institutions, technology) between a TIS and a specific context structure; while external links are influences, resources, or assets shared between a TIS and a specific context, such as national innovation policy or market conditions.

The specific objectives of the case studies were:

1. to provide insight into the drivers of, and barriers to, knowledge development and exchange among actors in the TIS and
2. to identify contextual factors that influence knowledge dynamics in the TIS.

2. METHODOLOGY

The case study's design drew from the theory on case selection, field study design, data analysis and validity, and shaping hypothesis from Eisenhardt [13], Yin [14], and Gibbert [15] and from the mixed method study approach of Lander [3]. The case population – i.e., relevant actors – had previously been identified through actor-collaboration networks based on scientific publications [16] and patents [17]. Two cases were examined:

1. Translational collaborations: Described as inter-sectoral collaboration between the university, healthcare, and industry sectors. The sectors serve the system in different ways and comprise organisations with different mandates; their motives for participating in knowledge production in the orthopaedic devices TIS (OD-TIS) may differ, and they typically provide complementary skills and resources. The case population was identified as the grouping of actors present in the actor-collaboration networks, and these co-authors and co-inventors from the source publications were invited to participate in the study.

2. Author-inventors: Individuals who appear in both scientific publication and patent actor-collaboration networks; these actors produce different types of knowledge (scientific discovery and technological application). This case explored development within, and knowledge translation between, the scientific and technological domains.

The primary data source was semi-structured interviews with individuals who met the case criteria. The interview questions comprised diagnostic questions for analysing TIS knowledge functions [18]. Ethical approval was obtained from the Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town (HREC 860/2015). In total, nine positive responses were received out of 32 e-mail invitations (a response rate of 28%). Secondary data was used to support the hypotheses developed from the interviews, and included actor-collaboration networks, an institutional review, and published literature.

3. FINDINGS

3.1. Case studies

The demographic data of the interviewees are presented in Table 1. Interviewees are referred to by aliases, in the chronological order of the interviews (P1, P2, etc.). Discussions initially focused on the development phase of orthopaedic devices, and how knowledge is created and exchanged among actors. The interviewees' experiences also revealed insights into the manufacture and commercialisation of devices.

A between-case comparison of the findings about knowledge functions is presented in

Table 2. The comparison is made on the basis of the types of development, choices in publishing and patenting, inter-sectoral collaboration, arenas for knowledge exchange, knowledge exchange as captured in the actor-collaboration networks, university-industry interactions, and barriers to collaboration with university actors.

Table 1: Demographic and relational details of interviewees from the two cases

Case	Alias	Highest academic qualification	Primary professional designation	Position held in current setting	Sector represented in network	Experience
Translation collaboration case	P1*	PhD	Engineer	Managing director	Industry	31 years in medical device industry
	P2*,Δ	MSc	Engineer	Chief executive officer	Industry	23 years in medical device industry
	P3*,Δ	MSc, MBA	Engineer	Founder/ Director	Industry	7 years in medical device industry
	P4*	DSc	Scientist	Retired	Industry	40+ years in medical device industry
	P5*	DSc	Surgeon	Surgeon (in private practice)	University/ Healthcare	50+ years in medicine and 40 years in medical device development

Case	Alias	Highest academic qualification	Primary professional designation	Position held in current setting	Sector represented in network	Experience
Author-inventor case	P6	PhD	Engineer	University professor	University/ Industry	26 years in biomedical research; 15 years in medical device industry
	P7	PhD	Engineer	University lecturer	University	10 years in biomedical research
	P8	DSc	Engineer	Chief executive officer	University	32 years in biomedical research; 20 years in medical device industry
	P9	PhD	Engineer	University associate professor	University	12 years in biomedical research

* Patent co-inventors in the actor-collaboration network
Δ Scientific publication co-authors in the actor-collaboration network

Table 2: A between-case comparison of knowledge development and knowledge diffusion through networks

Findings	Translational collaboration case	Author-inventor case
Types of development	• Orthopaedic software, instrumentation, biomaterials, plates, prostheses of major and minor joints.	• Two modes of knowledge development: (1) post-graduate student projects; (2) establishment of specialised facilities.
Choices in patenting and publishing	• Patenting in South African universities is a relatively new concept. • Industry rarely co-authors scientific publications. • Patents only reflect a portion of development activity.	• "Patent first, publish after, that's the rule here" – P7; a sentiment shared by all of the author-inventors. • Patent secured when commercialisation of the device was expected to be fast; patent offered design protection prior to market launch.

Findings	Translational collaboration case	Author-inventor case
Inter-sectoral collaboration for orthopaedic device development	• Devices developed collaboratively between engineers/technicians and surgeons. • Biomedical engineers provide interface between traditional engineers (mechanical, electrical, etc.) and clinicians.	• Devices developed collaboratively between (academic) engineers and clinicians from public and private healthcare; clinicians were often university-affiliated. • Initial collaborations fostered networks with additional clinicians, resulting in increased research directions towards improving surgical experiences. • Clinical collaborator absenteeism is a potential barrier to device development. • Industry actor's presence is not necessary for development; once IP has been secured, it can be licensed to a manufacturer.
Arenas for (tacit) knowledge exchange	• Mechanical workshops and operating theatres.	• Operating theatres where (academic) engineers are exposed to surgical techniques, allowing generic solutions to be updated; knowledge-sharing extended to students and mentees. • Mechanical workshops and motion laboratories.
Knowledge exchange captured in actor-collaboration networks	• Not a true reflection of actors' contributions to the OD-TIS.	• Networks did not reflect all intra-sectoral collaborations, resulting in an apparent disconnect between national universities.
University-industry interactions	• Industry actors share knowledge with the orthopaedic community at conferences/congresses and by inviting surgeons to their facilities. • University actors shared expertise or specialised equipment that was otherwise out of reach of industry actors. • Industry links to university include serving as external examiners of theses, and guest lecturing.	• Industry actors access university resources, and university actors build the national medical device industry through start-ups and spin-offs. • Industry provides financial resources to build facilities at the university, with the intent of accessing the facility.
Barriers to collaboration with university actors	• Long development turn-around times, unreasonable fees, burdensome administration, and IP ownership barriers.	• University IP ownership discourages clinicians from collaborative research. • Overall, interviewees were positive about university's role in the OD-TIS. Barriers highlighted by other sectors were acknowledged; however, intra- and inter-sectoral collaboration was now a regular occurrence, delivering positive outcomes.

The findings related to knowledge functions that were unique to each case are presented in Table 3. In the translational collaboration case, knowledge was created in the clinical performance of the device, predominantly through the device support evidence required by medical insurance companies. Knowledge was also developed by expanding the applications of the device beyond its intended use, and knowledge was positively enhanced by innovation in other fields (e.g., additive manufacturing and biomaterials). These findings reveal the nature of developments and the influence of industry actors. In the author-inventor case, knowledge development and exchange were largely initiated by intra-sectoral collaboration opportunities. The teaching responsibilities of university actors also advanced knowledge development. Barriers to university intra-sectoral collaboration still exist in the form of researchers being unwilling to collaborate and of cultural differences between universities.

Table 3: Unique findings of knowledge development and knowledge diffusion through networks in each case

Translational collaboration case	Author-inventor case
1. Knowledge development continues into clinical performance of devices; mainly motivated by evidence requirements of medical insurance companies. 2. Knowledge development extended beyond intended use – e.g., dental, maxillo-facial, and veterinary applications. 3. Knowledge development driven by innovation in allied field – e.g., additive manufacturing and biomaterials. 4. International knowledge exchange includes: international conference presentations, international surgeons performing local surgeries with local devices, market formation in other countries (selling IP to MNCs, enabling clinical device trials, commercialisation in new markets).	1. Intra-sectoral collaboration among university actors includes: joint supervision of post-graduate students, curriculum advice, thesis examination, joint workshops and training, joint conferences, mutual access to laboratory facilities, student exchange programmes, visiting professorships, and sabbaticals spent at other universities. 2. Barriers to university intra-sectoral collaboration still exist, in the form of researchers being unwilling to collaborate and cultural differences between universities. 3. Teaching responsibilities at universities enabled knowledge development and exchange, including expanding the curriculum to include principles of IP, and expanding the reach to clinicians.

The interview findings were grouped according to the TIS-contextual factor categories of Bergek *et al*. [12] in

Table 4. The knowledge functions were most strongly influenced by the sectoral context, driven by developments between the engineer and the surgeon and the various arenas for knowledge exchange. They were also linked to the activities taking place in related TISs and by geographical contexts. No political contextual factors were raised by the interviewees.

Table 4: Knowledge development and knowledge diffusion through networks grouped according to the TIS-contextual factors [12]

	Embedded TIS	Sectoral context	Geographical context
Knowledge development	Occurs alongside innovation in allied fields – e.g., additive manufacturing and biomaterials.	Industry actors seldom participate in scientific publications.	Clinical trials for FDA approval of a device were performed in the USA.
		University actors have a limited role in the OD-TIS.	National and international funding agencies support the establishment of facilities, device development, and knowledge exchange activities.

	Embedded TIS	Sectoral context	Geographical context
Knowledge diffusion through networks		Industry actors present developments at academic conferences and congresses.	Developments presented at international conferences.
		Devices are developed by collaborating surgeons and engineers.	Locally developed devices are taken to international markets, or IP is sold to international manufacturers.
		Arenas for tacit knowledge exchange include mechanical workshops, operating theatres, conferences and congresses, industry facility visits, and lecturing.	Collaboration with international universities enabled access to specialists to establish local facilities.
		Arenas for codified knowledge exchange include thesis examination and journal review.	Collaboration with international universities is based on common research interests.
		University and industry actors collaborate to establish specialised facilities.	
		University and healthcare actors collaborate in post-graduate student projects. Healthcare actors act as co-supervisors and provide access to resources.	
		Universities usually own IP in collaborative projects; this discourages collaboration with other sectors.	
		There are operating barriers between engineers and surgeons in collaboration. Education on how actors from other sectors operate is needed in collaboration.	

3.2. Institutional review

The interviewee results revealed that knowledge functions were not coupled to the political context. Institutional documents, however, painted a different picture. The government enables and facilitates medical device industry growth in South Africa. Government departments have their goals aligned to the National Development Plan Vision 2030 (NDPV-2030) [19], which outlines socio-economic development goals. The NDPV-2030 identifies 11 focus areas, including 'improving health', where medical devices play a role. Table 5 lists the major contributions made by government departments, particularly the Department of Science and Innovation (DSI) and the Department of Trade and Industry (DTI). These institutional documents largely reflect changes made in the National System of Innovation (NSI) in South Africa, and their effect on the OD-TIS.

Table 5: Institutional review of the policies of the Department of Science and Innovation and the Department of Trade and Industry to promote medical device innovation

Department of Science and Innovation (DSI)	Department of Trade and Industry (DTI)

Ten-year plan for Science and Technology [20]:
• Transform South Africa from resource-based to knowledge-based economy.
• Establish the Technology Innovation Agency (TIA) to address: fragmentation of funding instruments; establishment of an IP management office for IP protection, technology licences, and commercialisation.
Intellectual Property Rights from Publicly Financed Research and Development (IPRFRD) Act, Act 51 of 2008:
• Enable publicly financed IP generated from R&D to be identified, protected, used, and commercialised for the benefit of South Africans.
• Establish the National Intellectual Property Management Office (NIPMO) and Technology Transfer Offices (TTOs) at publicly financed research organisations, within 12 months of enactment of the Act.
Technology Innovation Act, Act 26 of 2008:
• Established TIA with the intention to promote the development and exploitation of innovations that are in the public interest.
• TIA complements NIPMO by promoting technology transfer and commercialisation by South African research organisations [21].
• Objectives of TIA's health focus area [22]:
  ○ Investing in the development of affordable and adaptable novel health technologies that address the local burden of disease;
  ○ Strengthening the current portfolio of health technologies, developing point-of-care diagnostics for tuberculosis, and exploiting expertise in cardiac and orthopaedic devices in South Africa
  ○ The development of a Technology Innovation Cluster Programme (TICP) to promote collaborative initiatives between university, industry, and government, to enable high-impact industrialisation in the sector. This has been transformed into the Medical Device and Diagnostic Innovation Cluster (MeDDIC), managed by the SAMRC, funded by TIA, and supported by the CSIR. SAMED and MDMSA are involved, as well as the IDC, DTIC, NDoH and National Treasury. This programme is also linked to PATH through the Global
	A strategic objective of the DTI is to grow manufacturing in South Africa for industrial development, job creation, investment, and exports. Strategies for building a medical device industry have been addressed in the Industrial Policy Action Plan (IPAP) since 2014. The IPAP identifies opportunities and the development of programmes [25-30]:
	• Strategy development for medical device sectors, including stakeholders from government, industry, labour, universities, and NGOs. The focus was to optimise manufacturing and trade in the sector; meet government's health needs; decrease the sector's trade deficit; and support the design of regulatory and economic measures to exploit the potential of the medical device and pharmaceutical industries.
	• The absence of a medical devices certification authority was impeding exports. This led to the facilitation of the development of regulatory standards and certification in South Africa and the facilitation of the development of support mechanisms to subsidise compliance with ISO13485. These interventions would address challenges and opportunities in the sector, including quality assurance, public and private procurement, and exports promotion, and enable import substitution.
	• Expanding co-operation and exports of medical devices to SADC and African markets, and leveraging BRICS status.
	• Optimising procurement processes of medical consumables in the public sector and the development of a programme in collaboration with the private sector to capture an increasing share of the private market.

Department of Science and Innovation (DSI)	Department of Trade and Industry (DTI)
Health Innovation Accelerator of the SAMRC. The bio-economy strategy [23]: • The first national strategy to present a plan for medical device development in South Africa. • Recommends a quadruple helix model of innovation approach: government provides the framework to co-ordinate relationships; industry has a key role in production; universities generate new knowledge, innovation, and technology; and civil society is consulted as co-innovators, end-users, and holders of traditional knowledge. • The NDoH sets the health research and innovation priorities for the strategy. The White Paper on Science, Technology, and Innovation [24]: • Sets the medium- to long-term policy direction of government for science, technology, and innovation policy; implemented through a series of decadal plans to be developed with multiple stakeholders (government, universities, industry, and civil society). • Provides supportive legislative environment for new industries – e.g., government procurement.	

3.3. Development of theory

The interview findings suggested that there were multiple perspectives on some topics, while in other instances the findings converged on a single perspective. The development of theory, presented here as propositions, is strengthened by triangulation with secondary sources. These propositions set the scene for a broader discussion in the next section.

3.3.1. Proposition 1: Inter-sectoral collaboration supports orthopaedic device innovation

The interviewees described different types of inter-sectoral collaboration, and they acknowledged that successful innovation arises from collaboration across sectors, particularly between engineers/technicians and surgeons. Inter-sectoral knowledge exchange is largely tacit, including conferences and congresses, operating theatres and mechanical workshops, thesis examinations, and lecturing. Both cases reported developments in the absence of a specific sector. In the translational collaboration case, the interviewees mentioned that developments largely occurred in the absence of university actors; in the author-inventor case, developments occurred in the absence of industry actors. In both cases, however, the healthcare actor was highlighted as being a significant actor in the development of orthopaedic devices. The proposition of inter-sectoral collaboration supporting orthopaedic device development was shown in the actor collaboration networks [16,17] and in the available literature [31, 32]. Locally, Chimhundu *et al*. [4] found that inter-sectoral collaboration between the university and healthcare sectors was the most prominent collaboration type in scientific knowledge production for cardiovascular medical device development in South Africa, while de Jager *et al*. [5] found that the university and healthcare sectors collaborated extensively both intra- and inter-sectorally in developing medical devices in South Africa.

Only about 15% of the publications in the publication and patent actor-collaboration networks emanated from translational collaboration, which suggested that orthopaedic device development can take place in the absence of translational collaboration across the three sectors.

There are also barriers to inter-sectoral collaboration, which include unmatched expectations from partners, different perspectives on IP ownership, and burdensome university administrative processes. Education about the roles and limitations of each sector in the collaborative partnership is necessary to address these barriers.

3.3.2. Proposition 2: The university sector has an important but limited role in the OD-TIS

Even though university actors were absent in both cases, they still played a role. In the translational collaboration case, they provide access to infrastructure that industry could not afford to build, while their absence from the author-inventor case was attributed to device development never reaching commercial implementation, as opposed to a complete absence.

Developments from universities often end with research or early-stage development (Technology Readiness Level 1 or 2) [33], with TTOs playing a role in liaising with industry to develop and commercialise the technology further. From the actor-collaboration networks [16], universities were instrumental in developing knowledge and diffusing it through the network. The industry actors who collaborate with university actors in scientific knowledge production were largely multinational corporations (MNCs) and South African entities running local operations of the MNCs. This suggests that national university actors are attractive to MNCs collaborators for scientific knowledge production. As these MNCs do not appear in the patent actor-collaboration network [17], it suggests that national university actors are sought for their early-phase research and development discoveries. In the patent actor-collaboration network, only seven national universities are represented, and the creation of spin-off companies to develop and commercialise technology is evident. This evidence from the actor-collaboration networks shows that the university has an important role in knowledge development and exchange in the OD-TIS, while the interviews showed this role to be limited.

3.3.3. Proposition 3: The healthcare sector has an important role in knowledge development

In addition to identifying clinical needs, healthcare actors conceive design ideas and provide practical recommendations for implementing designs and surgical techniques. Healthcare actors also have specialised resources and infrastructure, including operating theatres and access to patients.

In the scientific publication actor-collaboration networks, healthcare actors with a high degree of centrality were academic hospitals with close ties to research-intensive universities [16]; in the patent-collaboration network, many healthcare actors were private sector clinicians who patent in isolation [17]. Chimhundu *et al.* [4] and De Jager *et al.* [5] found the healthcare sector to be a significant contributor to medical device development in South Africa. This echoed the findings of Hicks and Katz [34], who found that hospitals served as an application site for biomedical research in the UK research system and that hospitals made a more substantial contribution than industry to the science base in the biomedical innovation system.

Despite these findings showing their important contribution, the healthcare actor as an innovator is not acknowledged in institutional policy. The South African medical devices ecosystem [35] considers the role of healthcare actors to be limited to identifying local needs and using medical devices, while the bio-economy strategy [23] does not explicitly include healthcare as one of the helices in its employment of the quadruple helix innovation model. In addition, the health professional standards prevent health professionals from being involved in any commercial activity (manufacture, promotion, sales, etc.) related to medicines or medical devices [36]. Orthopaedic surgeons acting as consultants to industry and so providing a genuine service can receive reasonable compensation for their services. Industry-sponsored health research was previously seen as inappropriate because of the bias it may have introduced. The South African Orthopaedic Association's *Principles of medical ethics* outlines sponsorship and remuneration details for health researchers, research organisations, and funding corporations [37].

3.3.4. Proposition 4: Knowledge development and exchange create legitimacy to support the acceptance of developed devices

Legitimation is the socio-political process of creating legitimacy for technology through the actions of actors, and is required for the formation of new industries and TISs [38]. It is necessary for resource mobilisation, demand creation, and attainment of political strength by actors in the TIS [39]. In the interviews, four scenarios were reported as creating legitimacy for orthopaedic devices:

1. Knowledge created on the clinical performance of the device for reimbursement by medical insurance companies.

2. Knowledge created to show the acceptable clinical performance of novel implants.

3. Knowledge created through clinical trials for Food and Drug Administration (FDA) approval to expand markets.

4. Knowledge developed and exchanged by key orthopaedic surgeons to endorse or demonstrate a device; this was often shared at conferences/congresses, which were an arena to promote the technology.

Medical device markets have regulatory requirements that must be met before the device can be sold. The South African Health Product Regulatory Authority (SAHPRA) – established in 2018 - has the responsibility of regulating medicines, complementary medicines, medical devices, radiation emitting devices, and radioactive nucleotides [40]. Before the 2016 amendment of the Medicines and Related Substances Act, there was no medical devices regulator in South Africa, and the sale and use of medical devices in South Africa was largely unregulated [41], with only electromagnetic medical devices or radiation-emitting devices being subject to certain regulatory criteria under the Hazardous Substances Act 15 of 1973. SAHPRA is still establishing the capacity to review and approve medical devices; in the interim, recognised regulatory approval, such as the European Conformity (CE) and the FDA, may be the quickest route to bring a product to the South African market [33]. Both the CE and FDA systems require knowledge development on the device for it to receive regulatory approval, a key form of legitimacy.

3.3.5. Proposition 5: Affordability of available devices is a driver of knowledge development

The author-inventor case revealed two instances in which knowledge development and exchange occurred owing to unaffordable market options that resulted in cost-effective alternatives being developed. Institutional policies showed that cost-effective innovations in medical device development, and health research in general, are encouraged or incentivised. This is evident in the National Health Act 61 of 2003, which mandates that cost-effectiveness be considered for interventions that reduce the burden of disease. The SAMRC has an agreement with PATH to promote *access to affordable and appropriate* medical devices, diagnostics, and vaccines in South Africa through research and development, technology transfer, and local manufacture [42]. TIA's health focus objectives include investing in the development of affordable and adaptable novel health technologies that address the Southern African burden of disease [22]. This institutional evidence illustrates how the government and its agencies are promoting cost-effective solutions in health technology research.

Proposition 5 exists alongside available resources as an enabler of knowledge development, which is an accepted feature of TISs and for which evidence was shown in the interviews.

3.3.6. Proposition 6: Knowledge development is enhanced by innovation in allied fields

Innovation in allied fields can be described by the function "development of positive externalities" [38], in which two or more emerging TISs are related if they share structural elements, and may mutually benefit from functions moulding these elements. This means that the strengthening of one TIS function may result in positive externalities that promote the development of the structural elements of another (related) TIS.

The interviews raised two points that indicated that knowledge created in the OD-TIS was enhanced by innovations in allied fields:

1. Advances in additive manufacturing (AM) resulted in advances in orthopaedic device development.

2. Advances in biomaterials enabled implant development.

AM is a process innovation, the implementation of which is expected to yield product gains through better-performing production processes. AM has made patient-specific orthopaedic implants realisable. The OD-TIS and the AM-TIS share structural elements in the form of actors (including infrastructure) and institutions. As an institution, the report *A South African additive manufacturing strategy* [43] speaks

explicitly to medical implants, including orthopaedic applications, promoting knowledge development and exchange among stakeholders for the use of AM platforms. South Africa already has an AM centre, The Centre for Rapid Prototyping and Manufacturing at the Central University of Technology (ISO 13485 accredited), which manufactures medical implants.

Through case studies, we explored aspects of knowledge development and exchange in the OD-TIS and proposed a theory that captures the findings from these studies.

4. DISCUSSION, CONCLUSION AND POLICY IMPLICATIONS

It is important to acknowledge here that the actor-collaboration networks are not sufficient to capture knowledge development and diffusion through networks. Co-authorship as a proxy for collaboration has been used extensively in social network studies, while co-inventorship has been used less extensively. The interviewees stated that the actor-collaboration networks based on these proxies did not truly capture knowledge development and exchange activity in the OD-TIS. Knowledge development and exchange activities not captured by scientific publications and patents were highlighted by the author-inventor case. The actors that facilitate knowledge development and exchange (e.g., TIA, NIPMO, SAHPRA) in the TIS were identified through the institutional review. Further roles of actors in the actor-collaboration networks were also discovered, thereby enriching the network and providing a more holistic picture. The case studies showed that, beyond R&D activity, knowledge development and exchange create legitimacy to support the acceptance of developed devices. This research has revealed some sources of knowledge exchange for the OD-TIS in South Africa; these include national conferences of importance to the orthopaedic community, joint meetings involving different stakeholders, and activity in mechanical workshops and operating theatres. Future studies of TIS knowledge development and exchange would benefit from an exploration of knowledge indicators derived from these sources, and from the development of approaches for their analysis.

The drivers of knowledge development and exchange were found to be: inter-sectoral collaboration; the availability of resources; the affordability of available devices; and the positive externalities of allied TISs. Actors from different sectors have different and defined roles in inter-sectoral collaboration, and successful developments arise when partners are aware of one another's mode of operation and have reasonable expectations from the collaboration. Funding enables knowledge development and exchange; it can translate into resources of other kinds, including human resources and infrastructure, which further advance knowledge development and exchange. The affordability of available devices stimulates innovation differently, resulting in more responsible use of resources with cost-effective solutions. In South Africa, the OD-TIS is structurally coupled to the AM-TIS. The horizontal linking between these TISs has shown that the maturation of each of them positively enhances that of the other. The main barriers to knowledge development and knowledge diffusion through networks of the OD-TIS were barriers to inter-sectoral collaboration.

Through the explicit consideration of context, an increased understanding of technology development in a TIS is achieved, and provides a basis for the classification, generalisation, and transfer of findings, which is important for TIS-based policy development. The TIS is structurally coupled to the embedded and sectoral contexts, and externally linked and structurally coupled to the political context. Sectoral dynamics influenced both forms of knowledge production. Science council actors such as the CSIR and SAMRC played a lesser role in creating knowledge, but were funders of medical device development and knowledge exchange initiatives, as well as creators of innovation pathways to facilitate technology transfer from publicly financed research. The bureaucratic nature of universities, accompanied by burdensome administration, dependence on an academic cycle, and unrealistic costs of research, discourages inter-sectoral collaboration. While healthcare actors are central to orthopaedic device development, they lack supportive institutions. This may be a deterrent to innovation by clinicians; however, a favourable pathway for healthcare actors to get their product to market – by serving as consultants to industry – was identified in the patent-collaboration networks [17].

The OD-TIS is part of the broader national system of innovation (NSI) in South Africa, and is affected by the innovation policy of various government departments. On the political front, government policy and medical device innovation initiatives have been introduced to promote knowledge development and exchange. However, clear causal pathways to the development of the OD-TIS could not be concluded, as an analysis of policy implementation was beyond the scope of the study. Nonetheless, an effect of the IPRPFR Act on behaviour change by university actors was suggested in the patent-collaboration networks

[17]. Patenting by universities is also expected to increase, with the DHET rewarding patents with equal weighting to journal articles in its revised research output policy. South Africa's NSI comprises a wide variety of institutions and organisations that play complementary roles in scientific and technological knowledge production [44]. The success of the TIS lies in having an institutional alignment between those policies that steer actor behaviour in the NSI and the specific policies that are geared towards the TIS. Actors who were not identified in the actor-collaboration networks but who play a role in the facilitation of knowledge development and exchange in the TIS include regulators that have the authority to establish pathways for technology development (i.e., NIPMO) and regulate markets (i.e., SAHPRA). While regulators appear to have their roles in the later stages of the innovation pipeline, being cognisant of their regulations is important in the earlier phases, as regulations dictate market entry and the consequent success of devices.

While government strategies co-ordinate inter-sectoral engagement among actors, healthcare actors must be recognised as knowledge creators in the innovation chain, and an institutional alignment of the sector with government strategy (e.g., the bio-economy strategy) should be implemented. The bio-economy strategy does not explicitly mention who the 'civil society' helix is in its quadruple helix model, even though civil society is considered to provide inputs as users of the innovations, hold traditional knowledge, and co-innovate through consultation. These characteristics overlap with those of clinicians and other healthcare professionals, as well as with NGOs and NPOs. Leaving the definition of 'civil society' broad has two consequences: (1) it excludes the healthcare sector from being a recognised helix in the proposed innovation model, despite its crucial role in medical device innovation; and (2) the institutions of healthcare actors may not expand and adapt to innovation policy or encourage innovation in the healthcare sector, causing a potential gap in the outcomes of the bio-economy strategy.

Government strategies such as the bio-economy strategy and the South African additive manufacturing strategy put forward mechanisms for stakeholders to participate in the innovation chain in a formal, coordinated way. The strategies draw on the skills, capabilities, and competitive/comparative advantages of actors. Over the past few years, government initiatives have emerged to support the medical device sector (the establishment of SAHPRA as a regulatory body); and other strategies have medical devices as streams that aim to accelerate the sector (medical device platforms in TIA, key action plans from the DTI, SAMRC and CSIR medical device programmes, initiatives, and platforms). These initiatives and interventions are still in the early stages of implementation, and are facing challenges, one of which is not having the (human resource) capacity to fulfil the ambitious tasks that lie ahead.

While the case studies were conducted before the SAMRC medical devices landscape report [1], and offer an in-depth exploration of the OD-TIS, the SAMRC report provides a comprehensive set of recommendations that extend beyond these studies. The SAMRC report offers actionable insights that are aimed at enhancing capabilities, fostering collaborations, and strengthening the regulatory and policy framework in the South African medical device sector. These recommendations include promoting and facilitating partnerships between science, technology, and innovation (STI) institutions and industry, enhancing technology readiness, and incentivising increased R&D investments by the industry in medical devices. In addition, the report suggests strategies for policy improvement and international collaboration, such as enhancing legislative and regulatory frameworks, designing new support mechanisms, and fostering bilateral R&D partnerships with targeted countries.

REFERENCES

[1] **SAMRC** 2022. The medical devices landscape in South Africa. [Online] Available at: https://www.samrc.ac.za/research-reports/samrc-medical-devices-landscape-report [Accessed 26 April 2024].

[2] **Deloitte** 2014. *Research to guide the development of strategy for the Medical Devices Sector of South Africa — Prepared in partnership with the DTI.* [Online] Available at: http://www.samed.org.za/DynamicData/LibraryDownloads/60.pdf [Accessed 9 February 2020].

[3] **Lander, B.** 2014. The role of institutions and capital in intersectoral collaboration: Infection and immunity research and development collaboration in Vancouver. *Review of Policy Research,* 31(5), pp. 390-406.

[4] **Chimhundu, C., De Jager, K. & Douglas, T.** 2015. Sectoral collaboration networks for cardiovascular medical device development in South Africa. *Scientometrics,* 105, pp. 1721-1741.

[5] **De Jager, K., Chimhundu, C., Saidi, T. & Douglas, T**. 2017. The medical device landscape in South Africa: Institutions, sectors and collaboration. *South African Journal of Science,* 113(5/6), pp. 1-8.

[6] **AMS** 2010. *Academia, industry and the NHS: Collaboration and innovation.* Meeting report. London: The Academy of Medical Sciences.
[7] **Mayosi, B., Flisher, A.J., Lalloo, U.G., Sitas, F., Tollman, S.M. & Bradshaw, D.**2009. The burden of non-communicable diseases in South Africa. *The Lancet,* 374(9693), pp. 934-947.
[8] **Hekkert, M., Suurs, R.A.A., Negro, S., Kuhlmann, S. & Smits, R.E.H.M.** 2007. Functions of innovation systems: A new approach for analysing technological change. *Technological Forecasting and Social Change,* 74, pp. 413-432.
[9] **Bergek, A., Jacobsson, S., Carlsson, B., Lindmark, S. & Rickne, A.** 2008. Analysing the functional dynamics of technological innovation systems: A scheme analysis. *Research Policy,* 37(3), pp. 407-429.
[10] **Blum, N., Bening, C. & Schmidt, T**. 2015. An analysis of remote electric mini-grids in Laos using the technological innovation systems approach. *Technological Forecasting & Social Change,* 95, pp. 218-233.
[11] **Jensen, M., Johnson, B., Lorenz, E. & Lundvall, B.-A**. 2016. Forms of knowledge and modes of innovation. In: B. Lundvall, ed. *The Learning Economy and the Economics of Hope*. London and New York: Anthem Press, pp. 155-182.
[12] **Bergek, A., Hekkert, M., Jacobsson, S., Markard, J., Sandén, B. & Truffer, B.** 2015. Technological innovation systems in contexts: Conceptualizing contextual structures and interaction dynamics. *Environmental Innovation and Societal Transitions,* 16, pp. 51–64.
[13] **Eisenhardt, K**. 1989. Building theories from case study research. *The Academy of Management Review,* 14(4), pp. 532-550.
[14] **Yin, R**. 2011. *Qualitative research from start to finish*. New York: The Guilford Press.
[15] **Gibbert, M.** 2015. *Case studies: A research strategy.* Stellenbosch.
[16] **Salie, F., De Jager, K., Dreher, C. & Douglas, T.S**. 2019. The scientific base for orthopaedic device development in South Africa: spatial and sectoral evolution of knowledge development. *Scientometrics*, 119, pp. 31-54.
[17] **Salie, F., De Jager, K. & Douglas, T.S**. 2021. Orthopaedic device innovation in South Africa: A study of patenting activity. *South African Journal of Science*, 117(5/6), Available at https://doi.org/10.17159/sajs.2021/8399.
[18] **Hekkert, M., Negro, S., Heimriks, G. & Harmsen, G**. 2011. *Technological innovation system analysis — A manual for analysts.* Utrecht: Universiteit Utrecht
[19] **National Planning Commission** 2012. *National Development Plan Vision 2030. Our future — Make it work.* [Online] Available at: https://www.poa.gov.za/news/Documents/NPC National Development Plan Vision 2030 -lo-res.pdf [Accessed 27 March 2019].
[20] **DST** 2008. *The ten-year plan for science and technology.* [Online] Available at: https://www.dst.gov.za/images/pdfs/The Ten-Year Plan for Science and Technology.pdf [Accessed 12 February 2020].
[21] **DST** n.d. *Department of Science and Technology strategic plan for the fiscal years 2011-2016.* [Online] Available at: https://www.dst.gov.za/images/pdfs/DST_STRAT_PLAN_2011.pdf [Accessed 12 February 2020].
[22] **TIA** 2018. *Health.* [Online] Available at: https://www.tia.org.za/health/ [Accessed 20 August 2019].
[23] **DST** 2013. *The bio-economy strategy.* [Online] Available at: https://www.gov.za/sites/default/files/gcis_document/201409/bioeconomy-strategya.pdf [Accessed 12 February 2020].
[24] **DST** 2019. *White paper on science, technology and innovation.* [Online] Available at: https://www.dst.gov.za/images/2019/WHITE_PAPER_ON_SCIENCE_AND_TECHNOLOGY_web.pdf [Accessed 12 February 2020].
[25] **DTI** 2014. *Industrial policy action plan: Economics sectors and employment cluster 2014/15 — 2016/17.* [Online] Available at: https://www.idc.co.za/wp-content/uploads/2019/02/IPAP2014.pdf [Accessed 18 February 2020].
[26] **DTI** 2015. *Industrial action policy plan 2015: Economic sectors, employment and infrastructure development cluster IPAP 2015/16 — 2017/18.* [Online] Available at: http://pmg-assets.s3-website-eu-west-1.amazonaws.com/150804IPAP2015.pdf [Accessed 18 February 2020].
[27] **DTI** 2016. *Industrial policy action plan IPAP 2016/17 — 2018/19 Economic sectors, employment and infrastructure development cluster.* [Online] Available at: https://www.gov.za/sites/default/files/gcis_document/201607/ipap-2016.pdf [Accessed 18 February 2020].
[28] **DTI** 2017. *Industrial policy action plan 2017/18 — 2019/20 Economic sectors, employment and infrastructure development cluster Part 1: A brief overview.* [Online] Available at: https://www.gov.za/sites/default/files/gcis_document/201705/ipap17181920.pdf [Accessed 18 February 2020].

[29] **DTI** 2017. *Industrial policy action plan 2017/18 — 2019/20 Economic sectors, employment and infrastructure development cluster Part 2: The engine room of change.* [Online] Available at: http://www.itac.org.za/upload/Industrial Policy Action Plan Part 2 17-18 - 19-20.pdf [Accessed 18 February 2020].

[30] **DTI** 2018. *Industrial policy action plan: Economic sectors, employment and infrastructure development cluster 2018/19 — 2020/2021.* [Online] Available at: https://www.gov.za/sites/default/files/gcis_document/201805/industrial-policy-action-plan.pdf [Accessed 18 February 2020].

[31] **Lander, B. & Atkinson-Grosjean, J**. 2011. Translational science and the hidden research system in universities and academic hospitals: A case study. *Social Science & Medicine,* 72(4), pp. 537-544.

[32] **Lander, B.** 2013. Sectoral collaboration in biomedical research and development. *Scientometrics,* 94, pp. 343-357.

[33] **University of Cape Town**. 2018. *Medical devices: An innovation guide from lab to commercialisation.* [Online] Available at: https://www.sarima.co.za/wp-content/uploads/2019/01/r2m_guide_01.pdf [Accessed 21 February 2020].

[34] **Hicks, D. & Katz, J.** 1996. Hospitals: The hidden research system. *Science and Public Policy,* 23(5), pp. 297-304.

[35] **Bunn, T**. 2018. *Initiatives to strengthen academia-industry linkages and grow the local manufacturing sector through medical device innovation and commercialisation.* Stellenbosch, South African Biomedical Engineering Conference.Available at: https://conference2017.csir.co.za/sites/default/files/Documents/Innovating transformative medical devices %26 growing the local manufacturing sector Bunn.pdf.

[36] **HPCSA** 2016. *Guidelines for good practice in the healthcare professions: Ethical and professional rules of the Health Professions Council of South Africa.* [Online] Available at: https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct %26 Ethics/Booklet 2 Generic Ethical Rules with anexures September 2016.pdf [Accessed 18 February 2020].

[37] **SAOA** 2019. *Principles of medical ethics.* [Online] Available at: https://saoa.org.za/about/medicalethics/ [Accessed 13 June 2019].

[38] **Bergek, A., Jacobsson, S. & Sanden, B**. 2008. 'Legitimation' and 'development of positive externalities': Two key processes in the formation phase of technological innovation systems'. *Technology Analysis & Strategic Management,* 20(5), pp. 575-592.

[39] **Aldrich, H. & Fiol**. 1994. Fools rush in? The institutional context of industry creation. *Academy of Management Review,* 19(4), pp. 645-670.

[40] **SAHPRA** 2019. *Annual performance plan for the fiscal year 2019/2020.* [Online] Available at: http://pmg-assets.s3-website-eu-west-1.amazonaws.com/SAHPRA_APP_2019_2020.pdf [Accessed 20 February 2020].

[41] **Saidi, T.** 2016. Towards a medical device regulation in South Africa: An assessment of the medicines and related substances amendment act of 2015. *Health Technology,* 6, pp. 83-88.

[42] **SAMRC and PATH**. 2014. *Developing an ecosystem to support the local medical device & diagnostics industry in South Africa — Recommendations from an international perspective* [Online] Available at: http://www.samed.org.za/Filemanager/userfiles/MRC-PATH- Medtronic Report 2014.pdf [Accessed 20 February 2020].

[43] **DST** 2016. *A South African additive manufacturing strategy.* [Online] Available at: https://www.dst.gov.za/images/2018/Additive Manufacturing Strategy.pdf [Accessed 12 February 2020].

[44] **Manzini, S.** 2012. The national system of innovation concept: An ontological review and critique. *South African Journal of Science,* 108(9/10), 1038.