







## **SUMMARY**

Advances in data-driven technologies such as artificial intelligence (AI) are transforming the health sector at an unprecedented rate. AI is enabling significant progress in healthcare, public health research, and drug development. In addition, AI has the potential to address issues around the broader social determinants of health by increasing access to health services, wellness and lifestyle management, and enabling efficient health systems management.

However, these advances also raise social, legal and ethical questions around the protection of personal information, equitable access to health care and patient safety, among others. It is therefore critical that South Africa develops and implements appropriate regulatory frameworks around the responsible use and governance of data and Al within the health sector. There is a substantial body of research and several global, multilateral and national policy frameworks that engage with critical policy issues in this field. In South Africa, the nature of these issues is complicated by high levels of poverty, a large disease burden and highly unequal resourcing and access to health services. This Topical Guide reviews the current

policy and research environment, with a view to adopting a more inclusive, human rights-based approach to the use of Al and data for improving health outcomes.

Specific recommendations include the development of national policies and strengthening key public interest institutions to:

- explicitly recognise and protect the human rights of patients and practitioners,
- 2. address issues related to data quality and bias,
- clarify mechanisms for ensuring safety and accountability in the context of automated decision-making,
- 4. explore ex-ante and ex-post approaches for improving the transparency of decisions,
- 5. understand the impact of data-driven technologies on trust and patient-centred care,
- 6. recognise concerns about automation and the need for skills development amongst healthcare workers,
- 7. seek ways for aligning the governance of data whilst recognising potential risks of broad data integration, and
- support existing work on language and translation for more user-centred AI systems.

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# **ABOUT THIS TOPICAL GUIDE**

This series of PAN Topical Guides seeks to provide key research insights and policy considerations for policy-makers, and other interested stakeholders, on how these technologies need to be developed, used and safeguarded in a manner that aligns with the transformation objectives of South Africa. In addition, each Guide outlines ways in which South Africa may respond to the growth of data-driven systems and technologies, including Al, to foster and inculcate a more inclusive and equitable society, rather than deepen divides.

The series is curated by the Policy Action Network (PAN), a project by the Human Sciences Research Council (HSRC) supported by the Department of Science and Innovation (DSI); and the University of Pretoria (UP) South African Sustainable Development Goals (SDG) Hub and Data Science for Social Impact Research Group, under the ABSA UP Chair of Data Science.

**Publication date: July 2020** 

# WHAT IS AI AND HOW IS IT RELEVANT TO HEALTH IN SOUTH AFRICA?

Artificial intelligence (AI) has been used to define various computerised systems designed to perform specific tasks generally associated with humans, such as learning, speech or visual recognition and problem solving. For the purposes of this guide, the term AI names the broad spectrum of technological systems with the ability to understand and continuously learn from data to perform tasks and make decisions with some degree of autonomy.

Currently, AI technologies are categorised into artificial narrow intelligence (ANI) and artificial general intelligence (AGI). The former describes AI that is designed for specific tasks such as those involved in chat bots or text recognition whilst AGI describes theoretical systems designed to reason across a variety of cross-cutting activities.<sup>2</sup> The majority of AI related health-care technology advances currently in use fall into the ANI category.

Machine learning (ML) techniques are a subset of AI systems and are used to train computer programs to recognise and learn from patterns in existing datasets. Through this relatively independent learning, MLbased systems make decisions that are often viewed by the user as analysing a set of data inputs and generating a number of classifications or recommendations. The internal mechanisms of how decisions are made by ML and other Al systems are often difficult to trace or understand by users and, in many cases, even the system developers as this becomes more advanced. This lack of interpretability is recognised as a key issue for the health sector and typically known as the "blackbox" effect.3

The adoption of AI is seen as an opportunity for organisations to function with greater efficiency and make better decisions.<sup>4</sup> The same can be true of the broader health

sector; from improving living conditions and promoting healthy lifestyles and wellness to post-treatment care and rehabilitation. More specifically, this technology is being used to diagnose and treat diseases; advance personalised medicine and drug development; monitor and predict the spread of disease and improve access to healthcare. Globally, AI (in one form or the other) is already being used to interpret medical image analysis to track the spread of cancer,<sup>5</sup> detect eye conditions using retinal imaging, 6 analyse data from personal monitoring devices,7 and to determine health insurance premiums and claim approvals.8 Figure 1 shows the adoption of AI and data in different domains of the health sector.



## **POPULATION HEALTH**

# Surveillance and prediction

- Map spread of disease
- Improve epidemiology monitoring
- Predict future outbreaks

### Population risk management

 Understand population risks to enable accurate projection of medical resource allocation

# Intervention selection and targeting

 Help define populations to target for interventions

# INDIVIDUAL HEALTH & WELLNESS

### Pathways to seeking care

 Real-time self referral, awareness, personalised outreach

#### Prevention

- Behavioural changes (diet, exercise)
- Wellness

#### **Diagnosis**

- Data driven
- Image based

#### **Treatment**

- Support clinical decision making
- Monitor compliance, adherence
- Palliative care

#### **HEALTH SYSTEM**

# Integrated electronic medical records

Analysis to assist in clinical decisions

# Capacity planning and resource management

 Predict and plan for the optimal allocation of capacity and resources

### **Quality assurance**

Analyse claims for error detection

### Fraud prevention

Recognise trends in claims

#### **Training**

 Facilitate real-time medical training for health care professionals

# BIOMEDICAL, PHARMACEUTICAL & THERAPEUTIC SERVICES

# Drug, vaccine and other therapeutics discovery

 Enables accurate and rapid genomic and proteomic analysis to develop targeted drugs

## **Drug safety testing**

• Optimise clinical trial support

### Supply chain optimisation

Improve supply chain and resource management

Augment and enhance research

Figure 1. Adoption of AI and data in different domains of the health sector

Government, industry and academia in South Africa have all highlighted potential benefits in adopting data and Al-driven applications within the broader health sector. <sup>10</sup> A recent report compiled by the University of Pretoria describes the potential of Al in several sectors, including healthcare, and suggests that Al can supplement the shortage of qualified healthcare

professionals and supplies, mitigate accessibility barriers and address rural and urban disparities in healthcare delivery. 11 Local technology firms are developing ML and AI for applications such as medical risk prediction and personalised medical diagnostics. 12

## Al and data in wellness: DrConnect from Discovery Health

Discovery Health started in SA in 1992 and was the pioneer in lifestyle management through the Discovery Vitality programme. Discovery Health's DrConnect<sup>13</sup> app is using Al technology to provide users with tailored assessments of medical symptoms, advice and remote support. Drawing on data relayed from wearable devices - including sleep, behavioural and mood data - this app uses Al to provide specific medical and lifestyle advice.

## Al and data to support the healthcare system in KwaZulu-Natal

Founded in 2003, BroadReach Healthcare developed a predictive ML-based system called Vantage. This was used to assess clinics' performance and make staffing or operational recommendations in HIV treatment clinics in KwaZulu-Natal. The system helped healthcare workers test 5.5 million people for HIV and start 530,000 people on anti-retroviral therapy from 2012 to 2018.<sup>14</sup>

## Al and data in scientific drug discovery: AlphaFold and COVID-19

Google's AlphaFold is being used by scientists to predict the protein structure of SARS-CoV-2, the virus that causes COVID-19.<sup>15</sup> This will provide a starting point for structure-guided vaccine discovery and understanding of COVID-19. Although the development of vaccine or treatment will need to undergo rigorous clinical testing (for safety and efficacy), the rapid analysis of these proteins would not have been possible without the use of Al.

Whilst there are a number of apparent benefits in using data and AI in health, there are several concerns around the ethical design and use of data-driven technologies which need to be addressed to ensure that the benefits of this technology outweigh the risks. Whilst the research on data and AI governance is expanding, and several countries have

developed strategies and regulatory instruments to guide technology adoption, the implementation of regulations and policy continues to lag technology-related changes.<sup>16</sup>

In South Africa, the Presidential Commission on the Fourth Industrial Revolution (4IR Commission) was tasked with reviewing relevant

policies, strategies and implementation plans to inform government's approach to the development and use of various converging technologies, including data and Al.<sup>17</sup> Whilst the recommendations of the 4IR Commission are likely to be influential, there are also pockets of Al and data-related policy discussion being led by certain line departments and agencies, such as by the Information Regulator through the Protection of Personal Information (POPI)

Act, 2013 (Act 4 of 2013),<sup>18</sup> and by the National Department of Health (NDoH) in the National Digital Health Strategy.<sup>19</sup> This Topical Guide provides an overview of some of the important national and international activity related to Al and data governance as it affects the health sector, and outlines a series of recommendations for policy actors to consider in seeking more equitable and inclusive benefit from these technologies.

# INTERNATIONAL PERSPECTIVES ON AI & DATA GOVERNANCE IN HEALTH

# Multi-lateral frameworks, strategies and policy think tanks

In a March 2020 draft of a Global Strategy on Digital Health, the WHO calls for an 'interoperable digital health ecosystem' supported by the 'seamless and secure exchange and processing of health data'. In this strategy, the sharing of data is seen to enhance the quality of processes and continuity of care, the linking of health data with other systems and registries, and 'secondary' data use in big data analytics and Al.<sup>20</sup> Due to the sensitive nature of health data, the draft calls for stringent technical safeguards and a strong regulatory and legal base to support enforcement of rules.

WHO work in this policy area is supported by an expert group which hosted an international consultation on ethics for AI in health in 2017<sup>21</sup> and recently published a dedicated WHO Bulletin exploring the ethics, governance and regulation of AI for health. Amongst other considerations, the Bulletin authors highlight:

• There is a need to strengthen ethics oversight for health research using Al. A large portion of Al-driven health research is exempt from higher education ethics committee scrutiny, and committees lack experience and confidence related to digital health. The authors of this article propose a two-layer, ex-post review of the use of Al in health research involving the posting of data and algorithms in open repositories, followed by validation of research processes and algorithms.<sup>22</sup>

- Recent progress towards a more patient-centric, empathy-driven model of healthcare may be undermined by a shift to Al-led decision making which focuses on efficiency and certainty, potentially reintroducing medical paternalism via technology.<sup>23</sup> Whilst automation could free up time for human interaction, it may also undermine the trust that patients have in health professionals.
- Al is challenging standard practices related to accountability for harm and in providing safety assurances.<sup>24</sup> This challenge is arising because health practitioners have limited control over the decisions that an Al-based system makes, and their understanding of how decisions are reached is limited due to lack of interpretability (as well as explainability) of many systems.

More broadly, concerns have been raised about the accuracy and limited regulation of an increasing number of automated, decision-support applications. This has resulted in calls for more structured evaluation of digital health interventions, including customised approaches for Al assessment, and a proposal by the ITU/WHO Focus Group on artificial intelligence for health (FG-Al4H) that countries adopt a transparent evaluation or assessment framework, using standardised, undisclosed data sets. Additional risks have been identified around race and gender bias in the collection and analysis of data, and related to personal privacy from data sharing.

Mitigating measures for privacy issues include the need for stringent informed consent regarding data collection and use, secure protection of data hosting environments, and strict controls over which data is shared and how. Echoing the WHO Bulletin above, issues of privacy and data sharing are especially relevant to health-related research, and is the subject of debate related to the POPI Act in South Africa.31 More broadly, a draft recommendation on the protection and use of health-related data published by the UN Special Rapporteur on the Right to Privacy – Task Force on Privacy and the Protection of Health-Related Data<sup>32</sup> calls for health-related privacy to be protected by default (privacy by default) and integrated into the design and use of information systems (privacy by design).

The Organisation for Economic Cooperation and Development (OECD) reflects WHO and other agency recommendations in calling for member states to recognise the unique risks to privacy and bias in the health sector (for example, in collecting biological data), and to minimise these risks by ensuring that necessary infrastructure, risk mitigation plan, stakeholder engagement and a national health data governance framework are in place to maximise the benefits and limit the risks of Al. They caution that the design and development of AI health applications should involve clinicians and health care professionals as this will be crucial for building trustworthiness around these systems.33

In its General Data Protection Regulation (GDPR), the European Union (EU) has already introduced a comprehensive legal framework for data protection. This framework details the rights of individuals (consent, data privacy, etc.), obligations of businesses (define and share how they will use personal data, data protection impact assessment, etc.), a plan of action in case of a data breach (data breach notifications, compensation to individuals, penalties, etc.), and extra limitations on the processing of 'special categories of personal data' including genetic data and data concerning health.34 The increasing use of 'big' data and AI in health settings increases the risk to privacy, such as by enabling re-identification of personal information by linking multiple data sets, meaning that existing approaches for gaining consent

and anonymisation are probably not sufficient.35 These formal frameworks and strategies are often developed or influenced by global expert groups, usually involving academics, as well as non-profit think tanks, privacy watchdogs and industry-driven ethics and principles. For example, OpenAI was founded by Elon Musk and a number of partners, and conducts research with a view to developing 'safe artificial intelligence', including in healthcare. As with many corporates working in AI, they have developed a Charter of principles to guide their work.36 The Brookings Institution has engaged with the health implications of AI directly and recommends investment in infrastructure for high quality, representative data; collaborative oversight by several health and regulation bodies: and augmentation of medical tertiary education to prepare health professionals to interpret and evaluate decisions made with the aid of Al systems.37 Finally, research groups such as the Future of Humanity Institute have championed the need for researchers to explore and adopt various practices and technical measures to guard against malicious use of AI,38 whilst Algorithm Watch has highlighted contradictions and challenges in (multi)national attempts to establish health data hubs that serve the Al sector.39

## **National strategies**

Numerous countries have developed national strategies for AI and data which address the use of these technologies in healthcare and the wider health system (including wellness and palliative care systems); including in the United Kingdom (UK), United States of America (US), India, Japan, China, Sweden and France.40 A common feature of these strategies is the acknowledgment of a significant role for governments in setting up an enabling system for the adoption and use of AI for the greater good of society. This includes governments playing a coordinating role in the regulation, stewardship and implementation of AI and data in health with support from academics and industry experts. In addition, national AI policies typically call on countries to significantly increase the funding available for Science, Technology, Engineering, Mathematics (STEM) education and research into Al. France, for instance, is planning to set aside EUR1.3 billion to develop

Al-led interventions, many of which have health related applications. As with many other regions, France's Al strategy is supported by greater sharing or 'pooling' of data, although the country expects to work within European frameworks for data protection to protect the privacy of users.<sup>41</sup>

The issue of patient safety is of paramount concern to a number of states when considering using AI with health data. Due to the black-box nature of AI, predicting potential hazards will be challenging as few users understand how these systems come to a decision. A key UK health body notes that there is currently too much uncertainty about accountability and responsibility around AI for it to be introduced safely, and suggests that AI developers in health-care should be treated like pharmaceutical

companies; by requiring licensing, post-market surveillance and procedures for the removal of unsafe systems. In addition, they recommend that clinicians, scientists and healthcare technicians should be involved in the whole chain of development of AI systems from design to testing and production.42 Taking this a step further, a set of US guidelines highlights the need for AI developers to use rigorous procedures for responsible design including documenting their methods and results.43 Requiring 'explainability' and the right to explanation is often seen as a way to make Al-driven decisionmaking more transparent<sup>44</sup> and empower end users or data subjects. However, there are concerns that this approach will only provide a superficial and, ultimately, inaccurate picture of what is going on in these systems.45

## Rwanda: Al and Data Innovation in Healthcare

Rwanda is considered an early adopter of emerging technologies, especially in the health sector, with supportive digital literacy initiatives and ICT policies.46 The country has hosted several international conferences addressing data and Al innovation in health, such as the Digital Health Hub in 2018<sup>47</sup> and an inaugural Data Science & Al Summit for Health (DASH) in Africa conference planned for 2020.<sup>48</sup> One of the country's high-profile initiatives in this field is a collaboration with Babylon, a London-based digital health service provider, which delivers smartphone-based triage and symptom checking to over 2 million registered users as a way to increase access to and affordability of healthcare. 49 The collaboration includes the use of public health facilities for laboratory tests and advanced consultations, and payment assistance via a government subsidised community insurance scheme. Babylon has completed pilots of an Al assistant to support these virtual consultations, and anticipates using data from the platform to predict outbreaks and epidemics. With the growth of digital health services in Rwanda, personal data protection has been recognised as a key issue, and a bill is due in the country's parliament.<sup>50</sup> Rwanda has also ratified the African Union (AU) Convention on Cyber Security and Personal Data Protection which defines limits on personal data reuse including the use of 'automated processing'.51 Through its relationship with the AU. Rwanda is also active in regional health data sharing initiatives. such as the Africa Centres for Disease Control and Prevention (Africa CDC) task force on the Ebola virus<sup>52</sup> and the African Union High Level Panel on Emerging Technologies (APET) which is exploring the role of AI in COVID-19 response.<sup>53</sup>

## India: National Strategy on Artificial Intelligence #AlforAll<sup>54</sup>

Developed by the National Institution for Transforming India (NITI Aayog), the National Strategy on AI (NSAI) is a wide ranging report which aims to inform AI research, promote adoption and address limitations around human capacity and skilling. This strategy prioritises AI adoption in healthcare and efforts to increase access, affordability and quality of healthcare and wellbeing. In this context AI is closely linked to technologies such as robotics and Internet of Medical Things (IoMT) as the new 'nervous system for healthcare' and a way to 'augment the scarce personnel and lab facilities; help overcome the barriers to access and solve the accessibility problem; through early detection, diagnostic, decision making and treatment'. Early detection of cancer is seen as a key opportunity area, and the agency is planning to establish a national repository of pathology images. The anticipated impact is similar to many developing countries, and so the NSAI notes that by addressing local healthcare challenges, such as early diagnosis of tuberculosis, the country will be in a position to export these solutions to Africa.<sup>55</sup> Key challenges for Al adoption include, amongst others, lack of data availability and sharing between health institutions, lack of formal regulation around anonymisation of data, and low awareness and skills related to Al. 56 As a way forward, the broad recommendations of the strategy include a call for more core and applied research in AI, skilling and reskilling of the workforce, creating multi-stakeholder partnerships to facilitate adoption of AI, and development of guidelines for 'responsible Al'.

## UK: Code of Conduct for Data-driven Health and Care Technology<sup>57</sup>

Following extensive engagement and deliberation with several stakeholders (including clinicians, academics, industry experts, policy makers and patient representative organisations), the UK's Department of Health and Social Care and the National Health Service (NHS) developed a code of conduct for data-driven health and care technology. This document outlines 10 principles which are heavily influenced by the UK's Data Protection Act 2018 and include (adapted from the original):

- 1. Understand users, their needs and context
- 2. Define the outcome and how the technology will contribute to it
- 3. Use data that is in line with appropriate guidelines for the purpose for which it is being used
- 4. Be fair, transparent and accountable about what data is being used: including using 'data protection-by-design' principles
- 5. Make use of open standards: including the NHS Digital standards on data collection, information standards, technology clinical safety standards and interoperability toolkit
- 6. Be transparent about the limitations of the data used (and algorithms employed)
- 7. Transparency about the type of algorithm deployed, how data is used, how performance will be validated and how it will be integrated into the care provision
- 8. Generate evidence of effectiveness for the intended use and value for money
- 9. Make security integral to the design
- 10. Define the commercial strategy

# THE SOUTH AFRICAN DIGITAL HEALTH CONTEXT

International concerns around the democratic and effective implementation of AI in health are compounded in SA by the severity of socioeconomic and infrastructural challenges, as well as the high levels of inequality in access to and funding of healthcare. For instance, 11% of households in rural areas are without access to electricity and only 10.4% of South Africans have internet access at home.58 Another barrier for deploying AI in healthcare in this setting is the limited availability of an AI or data-literate workforce and challenges with data quality.59 There are more specific issues relevant to providing healthcare in diverse contexts, such as language and translation barriers, in which cultural metaphors captured in patient notes will have to be 'deciphered'.60 In seeking a response to some of these challenges, researchers,

government and industry have made progress developing tools relevant to local needs and building digital policies that can guide Al and data use going forward.

A research report from the University of Pretoria and the Access Partnership highlights various opportunity areas related to the use of AI for improving healthcare in Africa,<sup>61</sup> and notes a number of research groups involved in AI-related technology development across the continent, including the Centre for AI Research (CAIR) in South Africa.<sup>62</sup> In addition, a number of South Africa-based start-ups and established companies are working on data-driven projects relevant to health.

**Cortex Logic** and its portfolio companies work across a spectrum of industries including healthcare. Specific Al-based applications within healthcare include: risk assessment for hospital benefit management, precision medicine for oncology and a therapeutic chatbot companion.<sup>63</sup>

**Phulukisa Health Solutions** is a start-up partnering with Microsoft and IOT Solutions to develop cloud-based and ML algorithms to detect and predict abnormalities in patient data. This is used to help triage and escalate emergency cases, aiming to limit the burden on the healthcare system.<sup>64</sup>

Whilst there may not be explicit AI policies for health in South Africa, a number of sector-specific and cross-cutting policies and legislation are relevant to the growing use of data and, in future, AI. Three examples are highlighted below.

• National Digital Health Strategy 2019-2024<sup>65</sup> aims to ensure that digital health interventions benefit patients (throughout the patient journey at either preventative, curative, palliative or a combination), healthcare workers and health systems managers. It seeks to use digital health technologies to augment the health system allowing more people to access quality health services whilst acknowledging that successful digital health implementation will require skilling and reskilling of the health workforce. The strategy anticipates AI, big data and predictive analytics supporting health system operation and evidence-based clinical decisions, and plans to develop a data science capability to guide technology adoption. The strategy's wider governance approach and objectives provide an important framework for guiding

- the adoption of data-driven services, and more details are outlined in the text box below.
- mHealth Strategy 2015-2019<sup>66</sup> recognises that mobile technologies, such as smart phones, provide new opportunities for collecting data 'where people live' and 'in real time' which can enable more effective and efficient health programmes. The strategy also notes that because personal data is now becoming more mobile, and not protected on relatively controlled central systems, that updated standards are critical.
- The National Health Act, 2003 (Act 61 of 2003) stipulates that the protection of patients' confidential medical information should be prioritised, including in the electronic transmission of personal medical information and data over networks. This protection of personal information is supported by the POPI Act and a variety of other pieces of digital and healthcare-related legislation which address the collection, usage, storage and processing of information.<sup>67</sup>

# Strategic Interventions of the South African National Digital Health Strategy 2019 – 2024<sup>68</sup>

The National Digital Health Strategy outlines nine strategic interventions aimed at supporting the adoption of digital technologies, most of which are directly relevant to data and AI use. For example:

- Develop leadership capacity for digital health innovation and adaptive
  management: includes identifying champions at all levels as change agents to drive
  digital 'transformation', and introducing a data-driven approach for adaptive leadership
  using business intelligence solutions.
- Undertake appropriate multi-stakeholder engagement for shared opportunities and successful digital health implementation: includes going beyond collecting data for reporting purposes, to involving a more diverse mix of stakeholders in deeper engagement with the information and extracting meaning.
- Review and strengthen governance structures and oversight mechanisms for the implementation of the strategy: includes aligning various digital health governance structures and implementing a data governance framework.
- Establish an integrated information architecture for interoperability and effective, safe sharing of health information across health systems and services: anticipates expanding the National Health Normative Standards Framework (HNSF) for Interoperability in eHealth to a Health Enterprise Architecture and common, shared digital health platform, on which 'sophisticated data science activities' may take place.
- Formulate national legislative, policy and regulatory framework for digital health: review existing digital health regulatory landscape and develop new regulations or supplement existing ones around data protection, data sharing between private and public sectors as well as cybersecurity.

# RECOMMENDATIONS FOR POLICY AND PRACTICE

Developments in data-driven technologies have the potential to enhance the quality and reach of healthcare services, improve wellness, diagnostics and surveillance of disease. Numerous studies and reports have raised concerns about, as well as and proposals for, the governance of data and AI in the broader health sector. Typically these have focused on ensuring valid consent for data collection and analysis, the protection of privacy, confidentiality and security, and appropriate mechanisms to monitor and deal with errors in data. 69 However, there are also the broader social implications of using AI and data in health such as trustworthiness of automated decision-making systems and how this affects patient relationships with health practitioners, as well as dangers

related to introducing or reinforcing existing biases associated with biological features such as race and gender.

South Africa's existing legislation and National Digital Health Strategy provide a useful starting point for AI and data governance in health by defining a number of key rules and making recommendations related to the collection and protection of health data, but also by calling for collaborative efforts to address concerns about the availability of digital infrastructure and skilled labour shortages. At the same time, there are several issues specifically related to AI and data use in health which can be addressed more explicitly:

- Recognition of human rights: Building on recommendations in the National Digital Health Strategy, there is an opportunity to deepen the enjoyment of and access to human rights for patients, health-care workers and health systems managers by explicitly recognising possible risks to specific human rights as outlined in the Constitution such as access to healthcare (section 27), access to information (section 32), dignity (section 10), equality (section 9), bodily security (section 12), life (section 11), and privacy (Section 14)<sup>70</sup> as well as the potential impact on healthcare professional employment.<sup>71</sup> This can be supported by the strategy's proposed multi-stakeholder approach to governance that empowers vulnerable actors and engages with local and indigenous knowledge systems.
- **Data quality and bias**: Researchers warn that poor data quality resulting from non-uniform or incomplete datasets, especially for more isolated and marginalised groups, will undermine the potential benefit of data-oriented technologies. Addressing this challenge will require ongoing investment in data collection capabilities and infrastructure at a grassroots level.<sup>72</sup> In addition, the majority of current AI implementations rely on learning from patterns in existing data, which tends to discriminate against certain population groups. Therefore, emerging technologies and associated policies need to ensure that suitable data (including synthetic data) and/ or alternative learning approaches are implemented to reduce the risk of bias.<sup>73</sup>
- Safety and accountability: As data-driven systems blur the responsibility for healthcare decision-making, so we need to find new ways for ensuring safety and defining accountability; including for health practitioners, policy officials and system developers. This includes clarifying the lines for reporting of and responding to adverse events such as data security breaches<sup>74</sup> or misdiagnoses with relevant oversight bodies. As noted, a number of researchers and policy actors are proposing the adoption of regulatory approaches for Al implementation that are similar to those used for pharmaceutical companies, such as pre-implementation testing using standardised datasets, post-implementation monitoring and procedures for the removal of unsafe systems.<sup>75</sup>

- Transparency: The models used by Al-based tools to make decisions are highly complex, opaque and often undecipherable by even the developers. Guidelines are needed for clarifying how, for example, a practitioner may override the recommendation of an Al-enabled decision support system. More broadly, research and implementation policies could require transparency about how data is collected and labelled, a description of limitations for systems assisting with clinical decision-making, independent peer review of algorithms and training of systems on validated datasets before implementation, publishing of data and algorithms to open repositories, public monitoring of impact, or support for explainability and the use of more interpretable models.
- Trust and patient-centred care: As Al-based systems come to mediate, augment or replace the interaction between healthcare practitioners and patients, there will be a need to understand how this impacts (both positively and negatively) efforts to support a more patient-centred approach to healthcare. In addition, research is needed into patient experiences of trust in relation to Al and how they affect trust between practitioner and patient. Building trust will also require increased public education about what Al is and its role within specific healthcare applications (as well as its limitations).
- **6 Implications for the health workforce**: A key issue for Al implementation will be to recognise the concerns of health workers, such as the perception that they will become redundant as more administrative and care functions are automated. Policy actors and technology implementors will need to clarify how data-driven platforms will augment (as often suggested) health practices and build trust with this community. This is also likely to include a need for developing new training programmes and skills for healthcare professionals, and a strategy will be needed on enhancing digital health human capital capabilities.
- Integration of data and governance: The National Digital Health Strategy envisages a common digital health platform. Aside from likely challenges with implementation, policy actors should be cautious about the level of data harvesting and integration between personal and health-related information and other 'big data' sources or platforms due to potential risks related to re-identification of individuals and use of personal data for purposes not consented to.<sup>80</sup> More broadly though, there would be benefits from increased consultation and appropriate institutions to support greater cross-sector collaboration, alignment of policies and enhanced trust to address current fragmentation.<sup>81</sup>
- **8 Language and translation**: In South Africa, the eleven official languages and linguistic subtleties will need to be taken into account when using AI technology for health, otherwise marginalised groups may experience further isolation. Significant research is being conducted by entities and groups such as Masakhane<sup>82</sup> and the South African Centre for Digital Language Resources (SADiLaR)<sup>83</sup> to develop machine translation for South African and African languages. However, as noted above, the nature of this challenge is complicated by specific practices and cultural metaphors which will need to be accurately interpreted by AI systems in order make the best decisions for patients.<sup>84</sup>

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