ETHICO-LEGAL ISSUES RELATED TO CAREGIVER-ASSISTED ORAL HIV SELF-TESTING OF CHILDREN 18 MONTHS – 12 YEARS IN SOUTH AFRICA

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DEDICATION

I dedicate this work to my dear husband and my three children who have supported me throughout this journey, who allowed us to sacrifice some of our quality time for this worthy cause.

DECLARATION

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ABSTRACT

In this study, ethical issues related to pre-and post-test counselling as well as informed consent when caregivers conduct HIV testing in children aged 18 months to 12 years using self-tests in South Africa were explored. Even though the legal requirements related to HIV testing of children in South Africa may be difficult to apply when caregivers use HIV self-tests in children, the study showed that consideration of this HIV testing approach would be in the child's best interests and that the protection of children's rights in South Africa facilitates both justice and children's best interests, including application of non-maleficence and beneficence principles. The study recommends the law on HIV testing of children be revised to make pre-test information optional and to consider HIVST as self-care which would make informed consent unnecessary when self-tests are used in children. More guidance is needed to help parents and guardians consider the views of children according to the children's evolving capacities when they use HIV self-tests in children. Despite the ethical concerns identified in the study, the researcher recommends caregiver-assisted use of HIV self-tests in children to address suboptimal HIV testing and low treatment rates in children living with HIV in South Africa.

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LIST OF ABBREVIATIONS

ART	antiretroviral therapy
CRC	Convention on the Rights of the Child
HIVSS	HIV self-screening
HIVST	HIV self-test
HTS	HIV testing services
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission (of HIV)
SMS	short messaging service
WHO	World Health Organization
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund

CHAPTER 1 – INTRODUCTION

1.1 Background and Context

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), new HIV infections diagnosed in children who are aged between 0 and 14 years declined from 320,000 in 2010 to 160,000 in 2021 (UNAIDS, 2022). Despite this achievement, only 52% of children infected with HIV were receiving antiretroviral therapy (ART) in 2021, which is significantly lower when compared with 76% of persons aged 15 years and older receiving ART (UNAIDS, 2022). Evidence suggests that missed opportunities for HIV testing in children may be responsible for poor outcomes, resulting in significant delays in diagnosis and initiation of ART (McCann et al., 2022).

In 2022, UNAIDS released a revised set of targets requiring the United Nations (UN) member states to work towards achieving the target of 95% of all those infected with HIV to know their status by 2025, while at least 95% of those diagnosed with HIV are started on ART and sustained on it, and finally, 95% of clients initiated on ART are sustained on it and are virally suppressed (Frescura et al., 2022). This HIV cascade is generally referred to as 95-95-95 targets. In South Africa, as of December 2022, the HIV cascade was 95-77-92 for the total population, and 83-48-33 for children aged 0-14 years (Sorour, Sipambo and Archary, 2023). The paediatric HIV cascade indicates that the coverage for ART in children was lower than that of adults, and to increase the much-needed ART coverage in children, HIV testing services for children need to be significantly strengthened (Van Rooyen, Strode and Slack, 2016).

For statistical purposes, UNAIDS has defined children as those aged 0-14 years old, while the youth and adolescents are those aged 15-24 years and 10-19 years respectively (UNAIDS, 2016). This study focused on children aged from 18 months, which is the age that marks the last routine HIV testing within the South African programme of prevention of mother-to-child transmission (PMTCT) of HIV, and up to 12 years, which is the minimum age of consent for HIV testing in South Africa. The study covered the age group of children who require parental or caregiver consent for HIV testing.

It is critical to test children for HIV because HIV testing is the gateway to accessing life-saving treatment services (Nuwagaba-Biribonwoha et al., 2019). Access to HIV testing leads to the identification of HIV-positive children, resulting in better and more effective care with reduced mortality (Van Rooyen, Strode and Slack, 2016). It is therefore important to highlight the fact that it would not be possible to access ART, which is a high-impact and life-saving intervention, unless the child has been tested for HIV. Evidence has also shown that early case finding and ART initiation in children could significantly reduce child mortality and slow disease progression (Wexler et al., 2020).

Even though most countries, including South Africa, have routinely implemented the facility-based HIV testing approach, there are still some barriers faced by children when they access facility-based HIV testing. These barriers include the reliance of children on parents or caregivers to take them to health facilities and the consent required for the HIV test (Dziva Chikwari et al., 2019). Operating times generally coincide with school hours, making it difficult for children to attend both. The significant gaps in paediatric case detection, especially among

older children and adolescents, call for policymakers to consider alternative HIV testing approaches for these children (Dziva Chikwari et al., 2019).

At the end of 2016, the World Health Organization (WHO) provided guidance on HIV self-testing (HIVST) and partner notification and defined HIVST as a testing modality that allows an individual to collect either blood or oral fluid as a specimen and use a simple HIV rapid test anywhere they wish to do the test and at their own time (World Health Organization, 2019). South Africa adopted HIVST that same year as an additional approach to HIV testing, aimed at expanding reach to the undiagnosed and under-tested adult population 18 years and older (National Department of Health, 2019).

South Africa's Children's Act (38 of 2005) has provided the legal framework for HIV testing in children, outlining four key principles, which are the best interests of the child, obtaining consent, providing counselling, and maintaining confidentiality (Van Rooyen, Strode and Slack, 2016). In this study, ethical issues related to pre-and post-test counselling as well as informed consent when caregivers conduct HIV testing in children using self-tests are discussed. Also explored is whether the caregiver-administered HIV testing approach in children using oral-based HIV self-tests would be in the best interests of children and if the principle of justice could be upheld.

According to the Children's Act (38 of 2005), a caregiver is defined as anyone who takes care of a child's needs and includes guardians, biological parents, foster parents, relatives, those heading childcare centres, and children 16 years and older heading child-headed households.

There have been calls to extend the use of HIVST in children to address the barriers to accessing HIV testing in children (McCann et al., 2022). Introducing the use of HIV self-testing kits in children by their caregivers is a possible intervention to be considered for mitigation of suboptimal HIV testing in children. However, HIVST is done privately by design with limited access to post-test counseling, which is a legal requirement for HIV testing in children in South Africa (Children's Act, 2005). Introducing such an intervention in children in the absence of post-test counseling raises some ethical concerns. Other related concerns include the extent to which the decision-making process by the caregiver for the next steps following a positive HIV test is adequately informed and whether limited access to such information would be in the best interests of the child. Considering these legal requirements, it is important to determine the ethical appropriateness of introducing caregiver-assisted HIV testing in children using HIV self-test kits in South Africa.

1.2 Overview of the Literature

1.2.1 Gaps in HIV Testing in Infants and Children

The prevention of mother-to-child transmission (PMTCT) of HIV programme in South Africa allows for children who are born to mothers who are infected with HIV to be routinely tested for HIV at birth, then at 10 weeks and 6 months after birth, thereafter at 6 weeks after the baby has stopped breastfeeding (Wessels et al., 2020). Over and above this testing schedule, all babies are tested for HIV at 18 months, regardless of the HIV status of the mother. The rationale behind this universal HIV testing at 18 months is to find HIV cases that could have been missed during

PMTCT (Wessels et al., 2020). Any child testing positive would be initiated on ART immediately.

The HIV testing conducted at 18 months of age for all infants marks the end of the PMTCT programmatic coverage for all children in South Africa (Ngandu et al., 2019). When children have aged out of the PMTCT programme, there are limited opportunities for systematic screening for HIV infection, especially among non-symptomatic healthy children, highlighting the need for alternative HIV testing approaches for children beyond the usual traditional settings designed for infant HIV testing (Simon et al., 2018).

Evidence also suggests that the PMTCT programme is likely to miss those children who are born to mothers infected with HIV who are not engaged in health care or are unaware of their HIV-positive status (McCann et al., 2022). Most of these children do not seek health care until they are older and have advanced HIV disease (Dziva Chikwari et al., 2021). It is therefore critical to expand the testing reach beyond traditional settings to find these HIV cases timeously. This study targeted children from 18 months to 12 years of age because first, there is currently no programme that routinely offers HIV testing to children older than 18 months and these children are dependent on caregivers for consent for HIV testing. Second, the reason for choosing the upper limit of 12 years is because it is the legal age of consent for HIV testing in South Africa.

A multi-country study conducted in 2021 in South Africa, Zimbabwe, and Côte d'Ivoire on the prevalence of undiagnosed HIV among children showed that, among children infected with HIV who were still alive by the age of 2 years, those that remained undiagnosed were 55.8%, 52.9%

and 44.2% in Côte d'Ivoire, Zimbabwe and South Africa respectively (McCann et al., 2022). The study highlighted the need to improve strategies for detecting cases of children living with HIV who remain undiagnosed beyond the age of 2 years, which is the period outside the PMTCT programme. To improve early diagnosis of missed HIV cases and the survival of more children who are living with HIV, the WHO recommends that countries consider testing approaches beyond traditional infant HIV testing programmes (McCann et al., 2022).

The 2022 South African National HIV Testing Policy has acknowledged the impact that HIV has had on the rights of children, and the policy highlighted the importance of allowing children to take part when decisions are made including the consent processes when they are tested for HIV (National Department of Health, 2015). The policy also emphasized that conducting HIV testing in a child should be based on the child's best interests (National Department of Health, 2015). The policy, however, provided recommendations that are based on traditional HIV testing, where the parent or guardian could give informed consent on behalf of the infant or the child. It is important to point out that the policy is silent on other alternative forms of HIV testing.

1.2.2 Oral-based HIV Self-testing in Children

WHO defines HIV self-testing as "A process in which a person collects his or her own specimen (oral fluid or blood) and then performs an HIV test and interprets the result, often in a private setting, either alone or with someone he or she trusts" (World Health Organization, 2019: p2). This study focuses on the oral-based HIVST, which means that the caregiver would have to swab the gums of the child to collect an oral fluid sample and test it for HIV using the self-test kit. The results would usually be available within minutes (World Health Organisation, 2019).

Two studies conducted in Zimbabwe and Kenya in 2018 compared the diagnostic performance of oral-based HIV self-tests with the traditional blood-based test in individuals aged between 18 months and 18 years (Dziva Chikwari et al., 2019). The researchers concluded that oral-based HIV self-tests were specific and sensitive enough to be used in children and adolescents, and they recommended that policymakers could consider expanding their use to include children aged above 18 months.

Another study conducted in Zimbabwe in 2020 assessed whether it was feasible for adult caregivers older than 18 years to conduct HIV testing in children using oral-based HIV self-tests, including the accuracy of such tests (Dziva Chikwari et al., 2021). The study researchers found that when caregivers administered oral HIV self-tests to children, the process was both accurate and feasible (Dziva Chikwari et al., 2021). In this study, the participant children had a median age of 8 years. While the study demonstrated that caregivers could perform the oral HIV self-testing in children independently and accurately, the findings also presented opportunities for task-sharing of HIV testing with caregivers to address constraints related to paediatric access to HIV testing (Dziva Chikwari et al., 2021).

1.2.3 Ethico-legal Considerations and the Use of HIV Self-Testing in Children

Philosophers Beauchamp and Childress (2019) have described 4 types of moral bioethical principles which could be applied when caregivers test children for HIV using self-tests. These principles are non-maleficence, beneficence, justice, and respect for autonomy.

The principle of non-maleficence refers to the responsibility not to inflict harm (Varkey, 2021). For all interventions, the healthcare worker is expected to weigh the benefits against the harms and to intentionally select those interventions with minimal burdens. Harm includes intentional or unintentional setting back of an individual's interests or what is to one's welfare advantage in that specific setting (Ghaly, 2015).

On the other hand, various authors have linked three elements with the principle of beneficence, which are: (1) the prevention of harm, (2) the removal of existing conditions that are harmful, (3) and the intentional promotion of good (Ghaly, 2015). The principle of beneficence is regarded as a maximizing principle that obligates one to protect patients and defend their rights while eliminating circumstances that may inflict harm (Varkey, 2021).

It is important to determine whether the act of providing HIV testing to children by the caregiver using an HIV self-test kit exerts sufficient effort in intentionally promoting the best interests of children and whether such an act can remove circumstances that may be harmful to the child. Beauchamp and Childress (2019) have also argued that such commitment to prevent harm should not be merged with that of doing good.

The principle of justice is understood in the context of appropriate treatment of persons, which is equitable and fair (Varkey, 2021). Two components of justice have been described, which are first, the equal treatment of those who are alike, and second, the fair distribution of both benefits and burdens which should also be equitable (Dhai, 2019). It is therefore critical to establish if the use of oral-based self-tests in children by caregivers involves a fair process for both the caregiver

and the child, and whether such action constitutes equitable access to HIV testing for children. Even though undiagnosed children living with HIV all have the same need to be tested for HIV and to be initiated on ART, there needs to be an understanding of what justice would mean for them. This is because infants and younger children exposed to HIV have different needs, varying degrees of vulnerability, and shifting capacities for engagement, compared to older children who are close to reaching 12 years, which is the legal age of consent in South Africa (Hayfron-Benjamin et al., 2018).

Respect for autonomy as a principle refers to a self-rule that is free of external interference, with the intentional provision of adequate information that allows for informed choices (Beauchamp and Childress, 2001). This principle is premised on the understanding that a competent individual, who has not been unduly influenced to make choices, does so intentionally and after being informed of possible benefits and risks (Motloba, 2018). For caregivers wishing to test their children for HIV using self-tests, this moral principle requires an acknowledgment of the right of caregivers to be autonomous, acting independently following a self-chosen plan. The caregivers must be assisted and be given full information to be competent in making autonomous choices related to the benefits and risks of various HIV testing modalities, including the use of self-tests (Dhai, 2019). They would also have to consent to possible harms and agree to accept the possible consequences of these actions (Varelius, 2006).

Based on the theories of philosopher Immanuel Kant, Kantian ethicists believe that human beings are special because they have autonomy and can freely decide how they want to act, which forms the basis for human dignity and rights, and that this autonomy is an intrinsic value

(Dhai and McQuoid-Mason, 2020). It is important to understand if the use of an alternative HIV testing approach, where caregivers conduct HIV testing in children using a self-test kit, can create options that support freedom and respect for an autonomous choice. According to Dhai and McQuoid-Mason (2020), such respect for autonomy would be realized when it can be demonstrated that they have acted voluntarily and made choices that were informed.

David McQuoid-Mason, a professor of Law in South Africa, has described patient autonomy as both ethical and legal in nature (McQuoid-Mason, 2012). Referring to the case of Dr. Conrad Murray who was charged with the death of the pop singer Michael Jackson for giving him propofol injection at his request, McQuoid-Mason highlighted the court's recognition that Jackson's request was done freely and intentionally by him. However, even though it seemed like Jackson's autonomy was respected by the doctor, the judge ruled that Jackson was not fully informed about the risks of taking propofol, and as a result, the consent he provided was not adequately informed. Dr. Conrad Murray was convicted of involuntary manslaughter by the Los Angeles County Superior Court (McQuoid-Mason, 2012). Relevant to caregiver-assisted HIV testing of children, this decision by the Los Angeles court highlights the importance of healthcare workers having to ensure that caregivers fully comprehend and can demonstrate understanding of the risks associated with using an HIV self-test in children, who are legally dependent on them in giving consent. However, it is not clear how consent can be adequately informed when HIV testing is conducted privately by caregivers without the presence of healthcare workers.

When faced with the dilemma of deciding whether the act of conducting HIV testing in children by caregivers using self-tests is morally right or wrong, a utilitarian approach would need one to determine which actions are available that would produce the greatest balance of happiness (Rachels and Rachels, 2019). Some philosophers like Jeremy Bentham and John Stuart Mill, who believed in the greatest happiness principle, have suggested that the wrongness or rightness of chosen actions is determined by whether the actions would result in maximum happiness while bringing less pain to most people (Tseng and Wang, 2021). Mill further described the factors against which this pain or pleasure is measured, which are extent, certainty, intensity, duration, remoteness, and purity (Mandal, Ponnambath and Parija, 2016).

Informed consent is a requirement for HIV testing in South Africa, regardless of the HIV testing approach used (National Department of Health, 2016). The case of *Castell v De Greef*, involving a patient who successfully sued the doctor for not fully disclosing complications and some material risks that were related to the surgery that was performed despite having given consent for the surgery, ushered informed consent into law in South Africa in 1994 (Castell v De Greef, 1994 (4) SA 408). The court ruling provided the standard of disclosure required for informed consent and emphasized that disclosure is an essential component of individual autonomy and the right of self-determination. This was later entrenched in Section 12 (2) of the Constitution of the Republic of South Africa, and it addressed the protection of autonomy or self-determination (South African Constitution, 1996). When considering the use of HIV self-tests in children, there is a need to establish how informed consent would be obtained from the caregiver if the test is performed privately.

1.3 Research Question

Evidence shows that 13% of children living with HIV who are undiagnosed in South Africa due to barriers to accessing traditional facility-based HIV testing are unable to access life-saving ART, resulting in high mortality from resultant advanced HIV disease (Sorour, Sipambo and Archary, 2023). All children living with HIV younger than 5 years and those older than 5 years with stage 3 or 4 of HIV disease are regarded as having advanced HIV disease (WHO, 2017). There is, therefore, a need to consider alternative HIV testing approaches for these children for timely diagnosis and mitigation of progression to advanced HIV disease.

My research question is: What are the key moral and ethical issues related to caregiver-assisted HIV self-testing in children aged between 18 months and 12 years in South Africa?

1.4 Rationale for the Study

The literature review showed that only 52% of children living with HIV were receiving ART in 2022 due to suboptimal HIV testing rates in children (UNAIDS, 2022). There are also challenges preventing children from accessing traditional HIV testing in health facilities, making a case for supporting alternative approaches to HIV testing in children.

Section 130 (2a) of South Africa's Children's Act 38 of 2005 has made provision for children above 12 years of age to access HIV testing services but left the younger children to the discretion of caregivers. Although the Act was aimed at protecting children from harm and promoting their best interests, it is not clear whether conducting HIV testing in children by caregivers using HIV self-tests would be in the best interests of children.

Foundational principles are needed against which caregivers can judge their actions to assist them in deciding what is the morally right thing to do. The existing literature broadly addresses issues related to HIV self-testing in children who can provide legal consent to HIV testing. There is a gap in the available research results for young children who are below the age of consent. It is envisaged that the findings of this study would inform policy and contribute to addressing suboptimal HIV testing in children, improving timely diagnosis and early ART initiation, with a resultant impact on the overall decline in paediatric AIDS deaths (Johnson et al., 2020).

1.5 Research Aim

The overall aim of the study was to describe and critically discuss ethico-legal issues related to HIV testing by caregivers in children aged 18 months to 12 years using self-testing kits.

1.6 Research Objectives

- To provide a critical and in-depth overview of the literature related to HIV testing in children by caregivers using self-test kits.
- To describe and discuss critically the ethico-legal issues related to the following:

  Ethical Issue 1: The ethical and legal permissibility of a caregiver conducting an HIV test using a self-test kit in children without any pre-and post-test counselling, as stipulated in the law.

  Ethical Issue 2: Ethical considerations for comprehensive informed consent required for patient autonomy when an HIV test is conducted in children.

Ethical Issue 3: Protection of the child's best interests and upholding the principles of non-maleficence and beneficence when caregivers conduct HIV testing in children using self-testing kits.

Ethical Issue 4: Ethical considerations for justice as fairness in processes related to HIV testing of children by their caregiver using self-test kits.

- To provide a summative analysis and normative evaluation of these ethical issues in relation to HIV testing by caregivers using HIV self-test kits in children in South Africa.

1.7 Research Methods

This was a normative study using desktop research and drawing from various data sources, such as MEDLINE, PubMed, EMBASE, CINAHL, books, journal articles, guidelines, and government policies and legislation. Various moral theories were used to analyse and interpret concepts and findings from the literature. These findings were critically and ethically analysed.

1.8 Argumentative Strategy

1.8.1 Key Ethical Issue 1:

Section 132 of the South Africa's Children's Act 38 of 2005 stipulates that when children are tested for HIV, there must be appropriate pre-test and post-test counselling for both the child and the caregiver provided by an appropriately trained person (Children's Act, 2005). The South African National HIV Testing Policy also states that a client who undergoes HIV testing should

be provided with brief pretest information and more detailed post-test counselling that is informed by the results of the HIV test (National Department of Health, 2016).

The related ethical concern was that the caregivers would most likely use the HIV self-tests in children at home and would not have access to appropriate post-test counselling delivered by a trained provider as required by law and stated in the South African HIV testing policy. This dilemma arises because HIV post-test counselling would be an opportunity to provide the caregiver with the critical information required to ensure that appropriate and autonomous choices are made for a child.

The dilemma was also related to the lack of alignment between the Children's Act requirements, which make counselling mandatory for HIV testing in children in South Africa, and the adoption and implementation of the HIVST policy by the government as an additional testing strategy to reach undiagnosed PLHIV, which allowed HIV testing to be conducted privately, with limited access to counselling (Van Rooyen, Strode and Slack, 2016).

1.8.2 Key Ethical Issue 2:

The South African National HIV Testing Policy allows children 12 years and above, with maturity, to give informed consent for accessing HIV testing services, but leaves the HIV testing of younger children to the discretion of someone else to make that decision for them (National Department of Health, 2015).

The court ruling in the case of *Castell v De Greef,* which was discussed earlier, redefined the nature of the disclosure required for lawful informed consent in medical settings by adopting a more patient-focused approach (Thomas, 2007). In this case, the judge used the word 'comprehensive' when referring to informed consent, suggesting that there must be an ongoing dialogue that continues even after the patient has consented, to allow for proper recognition of patient autonomy, and the judge referred to it as a patient-oriented approach to informed consent (Thomas, 2007).

The related main ethical concern is whether it would be possible to provide comprehensive information to the caregiver that supports consenting for HIV testing and to do so as an ongoing dialogue with the caregiver when such testing is conducted privately on the child using a self-test.

Based on the outcome of the case of *Castell v De Greef,* the caregiver, acting on behalf of the child to be tested and using an HIV self-test, must consent comprehensively and accept to go ahead with such an action despite all the possible risks and harms. Unfortunately, HIV self-tests may be accessed through various platforms outside health facilities, such as pharmacies and the internet, which are access points that do not provide counselling or comprehensive information about the risks and possible harms, as required for respect for autonomy.

1.8.3 Key Ethical Issue 3

The South African Constitution refers to the child's best interests as a constitutional right of every child and "…Of paramount importance in all matters concerning the child" (Constitution

of the Republic of South Africa, 1996: sections 28 (2)), while at the same time, section 10 of the Constitution addresses the inherent dignity as a right which must be protected and respected.

The Children's Act (38 of 2005) supports children's constitutional rights and adds that everyone who works with children must respect, protect, and promote the rights of the child (Children's Act, 2005). The Act also emphasizes the importance of ensuring that when a person conducts an HIV test on a child, it must be in the child's best interests. The caregiver is lawfully allowed in South Africa to consent to HIV testing on behalf of the child, however, the related ethical concern is whether such a test would be in the best interests of the child, given that the test would be conducted privately and with limited support from the health system. There is a risk that HIV testing by the caregiver in children using a self-test may expose children to testing for reasons other than those in the children's best interests.

Acknowledging that the caregiver has a right to autonomous choices must be balanced against the need to protect a child's well-being. Allowing caregivers to conduct HIV self-testing on children independently poses an ethical dilemma because of the risk of using children as mere means and the risk of stigma and discrimination, which may potentially compromise the principle of non-maleficence and violate the constitutional right of the child's best interests (Varkey, 2021).

1.8.4 Key Ethical Issue 4:

John Rawls, in his book, *A Theory of Justice*, has described the principle of justice as fairness, as the way a basic structure of society that is just is organised, which can distribute key benefits and

burdens of social life (1971). Rawls asserted that the concept of justice goes beyond distribution and requires broader connections to be considered to ensure that the protection against the violation of the rights of members of society is guaranteed through the basic structures of society.

As a principle, justice as fairness challenges the basic structures of society to ensure people are not exploited or coerced into submitting claims that are not true, and that when they participate in certain practices, they should be free and have the right to freedom available to everyone within the same system (Edor, 2020).

For justice to be fair, everyone must have a fair chance of accessing the benefits and burdens, regardless of their socio-economic status in society and other differences. Rawls also referred to this as the liberty principle, which simply means that the freedom to participate in any practice is a right that must be available to anyone similarly affected and not to a few selected individuals, which is what makes an action just and fair (Edor, 2020).

Therefore, when caregivers test their children for HIV using a self-test, there needs to be a way of establishing if such an action is just and fair, by exploring if other children in a similar position have a fair chance of being tested for HIV through the same testing approach, regardless of their different social class, and that no children can be exploited through such a process by having their caregiver consent to illegitimate claims about this testing approach (Rawls, 1999).

Some scholars have argued that the principle of justice should be prioritised over efficiency and welfare, highlighting the fact that fairness and equal opportunities should be considered before the principle of efficiency and the difference rule (Jamnik, 2021). Prioritisation of justice over efficiency implies that, even though there may be evidence of efficiency and benefit in HIVST as an approach to HIV testing amongst those who are underserved, for this intervention to be just, it would need to be demonstrated that if there are differences in the socio-economic statuses of caregivers or children to be tested, justice and fairness towards the children and the caregivers would take priority over the efficiency of the use of HIV self-tests in these children by their caregivers.

1.9 Research Outcomes

The findings of this research study will be shared with the National Department of Health of South Africa with the objective of contributing to policy reviews related to HIV testing in children. The outcome and recommendations will also be presented at least at two HIV conferences, including publication in one or more journals, with the aim of sharing the results more widely with other scientists, researchers, and programme managers.

1.10 Limitations of the Study

The study will focus on ethico-legal aspects of caregiver-administered oral-based HIV self-tests and will not include blood-based self-test kits.

1.11 Overview of Chapters

CHAPTER 1: **Introduction**: This chapter provides the background to the proposed study, including a brief overview of the review of the literature. The chapter also addresses the research question, objectives and rationale for the study, including study methods and the argumentative strategy.

CHAPTER 2: **Pre- and post-test counselling and HIV testing in children using self-tests:** This chapter discusses the ethico-legal issues related to counselling when caregivers use self-tests to conduct HIV testing in children. The chapter also outlines legal norms to be met which are related to counselling when testing children for HIV and applied to caregiver-assisted testing using self-tests.

CHAPTER 3: **Informed consent and patient autonomy in HIV testing in children using self-tests**: This chapter addresses the ethical concerns related to the provision of comprehensive and informed consent for HIV testing and how these impact on patient autonomy when children are tested for HIV by caregivers using the HIV self-tests.

CHAPTER 4: **Use of HIV self-tests in children and the child's best interests:** This chapter explores various theories and principles that could be applied when examining whether it is in the child's best interests to allow caregivers to test children for HIV using self-tests.

CHAPTER 5**: Justice as fairness**: This chapter outlines the various ethical issues related to justice and fairness for both the caregiver and the child when HIV testing is conducted by caregivers in children using self-tests.

CHAPTER 6: **Conclusions and Recommendations:** This chapter provides recommendations based on the summative analysis and normative evaluation of ethical and legal issues addressed in this study which are related to caregiver-assisted HIV testing of children using self-tests in South Africa.

CHAPTER 2 - PRE- AND POST-TEST COUNSELLING and HIV TESTING IN CHILDREN USING SELF-TESTS

One of the challenges posed by the HIV self-testing (HIVST) approach is related to inadequate pre-and post-test counselling, as well as difficulties in tracking the tests and reporting results to effectively link the users to appropriate HIV services and care (Fischer et al., 2023). In this chapter, I will outline the legal norms that need to be met when children are tested for HIV. I will then discuss the ethico-legal issues related to limited counselling that occurs when caregivers use self-tests to conduct HIV testing in children and apply these to determine the moral permissibility of caregiver-assisted use of self-tests in children.

2.1 Legal Framework on HIV Counselling in Children

HIV self-testing, by definition, covers any form of testing for HIV where a person collects their own sample and performs a simple, rapid HIV test, and as such, would be the first to quickly know the results, independent of a healthcare provider or facility (Mavedzenge, Baggaley and Corbett, 2013). For caregiver HIV testing of children using self-tests, this would mean that the caregiver would be the first to have access to the results in their private place.

Prior to 2005, HIV testing in children in South Africa was regulated through the general provisions of the Child Care Act (74 of 1983), which only focused on giving consent, and it was covered under the section on medical treatment in children. The reliance on this legislation was because, at the time, there were no laws that specifically dealt with HIV testing in children. The application of the Child Care Act (74 of 1983) to HIV testing in children was not adequate in protecting children against discriminatory testing, and its provisions could not enforce obtaining

consent for HIV testing of children who did not have parents who could consent on their behalf (Strode, Van Rooyen and Makusha, 2013). It was evident at the time that HIV testing was an area where the rights of children were open to abuse and that some legislation was needed to protect these children's rights.

The Children's Act (38 of 2005) came into force in June 2006, and it was the first legislation that specifically addressed HIV testing in children, separating it from other forms of medical treatment. It described in detail the conditions and circumstances under which children could be tested for HIV, and it explained how and when a child could be tested (Children's Act, 2005). Under sections 130-132, the Children's Act (2005) expressly articulates four distinct norms that regulate HIV testing of children in South Africa, which are as follows:

First, the Act describes the standards related to circumstances where children may be tested for HIV, which are that: (1) HIV testing may be conducted in the best interests of the child and conducting the test should include obtaining lawful consent, and, (2) HIV testing may be conducted when there is a need to establish the HIV status of the child in cases where someone else has been exposed to the body fluids of that child, for example, a health care worker who has been in contact with the child (Children's Act, 2005).

Second, the Act has expressly mentioned the requirements for counselling during HIV testing, stating that the child must be counselled before and after being tested for HIV. Third, the Act mentions that children who are 12 years and older and have sufficient maturity could consent

independently to HIV testing. Fourth and lastly, the Act stipulates that all children have a right to have their privacy respected (Children's Act, 2005).

In this chapter, I will address one of the four norms stated above, which relates to the legal requirements for counselling when children are tested for HIV. I will explore whether caregiver-assisted HIV testing of children using self-tests would be lawful by reflecting on the provisions of the Children's Act (2005) and other related legislation and health policies available in South Africa.

Section 132 of the Children's Act (2005) highlights issues related to counselling when children are tested for HIV, and it states that children have to be counselled by a trained provider before being tested for HIV. In addition, the Act suggests that counselling should be offered to both the child, if mature enough to understand the benefits and risks, and to the parent or guardian, if they know that the HIV test is being conducted (Children's Act, 2005). The Act further dictates that after an HIV test has been conducted, post-test counselling should also be offered to the child if of sufficient maturity and to the parent or caregiver as well if they are aware of such a test being conducted. This counselling is expected to be done by an appropriately trained provider. These counselling requirements for HIV testing of children indicate that in South Africa, both pre-and post-test counselling are a legal requirement for HIV testing in children, regardless of the approach and type of HIV testing offered to the caregiver and the child if the child is of sufficient maturity (Children's Act, 2005).

Even though the South African National HIV Self-Screening Guidelines (2018) emphasize the application of a rights-based approach to HIV self-testing in general, the same guidelines limit the use of HIV self-tests to individuals who are 18 years and older. As a result of this age restriction, there is no clear guidance on the use of HIV self-tests in individuals who are younger than 18 years of age, including children.

The South African National HIV Testing Services Policy (2016) includes pre-test information and post-test counselling as an essential part of HIV testing, regardless of the testing approach being used and for all ages. The policy also expresses the importance of counselling in children by stating that: "HIV testing must be accompanied by a correct pre-information session and post-test counselling done by an appropriately trained person. This provision ensures that children and their caregivers make appropriate choices regarding HIV testing" (National Department of Health, 2016: p.6). For caregiver-assisted HIV testing of children to be lawful when they use self-tests, unless they have expressly waived this right, children with maturity and their caregivers should be able to access both pre-test counselling as well as post-test counselling (Strode, Van Rooyen and Makusha, 2013).

2.2 Pre-test Information in Caregiver-assisted HIV Testing of Children Using Self-tests

In previous years, HIV samples that were collected for testing were sent to the laboratories for analysis and results could not be delivered on the same day, making elaborate pre-test counselling conducted routinely for all clients a necessity, which was aimed at encouraging them to return for their HIV results later (WHO, 2019). The pre-test counselling provided details on

the possible outcomes of the test and available services to support those who tested HIV-positive.

The recommendation for intense pre-test counselling was designed to protect the rights of those who were tested for HIV, and to prepare them psychologically for possible HIV-positive status. However, over time, the emergence of rapid diagnostic tests allowed for testing to be conducted at the point of care with results being available within minutes (WHO, 2019). Based on the availability of these rapid diagnostic tests, WHO reviewed its guidance and no longer advocated for individualised detailed HIV pre-test counselling. Instead, brief and concise pre-test information was recommended and sought to address the client's questions (WHO, 2019).

Therefore, the recommended brief pre-test information session could be an instrument for closing information gaps in those opting to take an HIV test, rather than being an opportunity for teaching clients about HIV.

According to WHO (2016), individuals presenting for HIV testing would have undergone HV testing before would have received pre-test information several times prior to the current testing event. In such cases, the pre-test session should be very brief and be used to respond to the client's questions (WHO, 2019). For caregiver-assisted HIV testing of children using self-tests, the brief pre-test information would also be applicable to caregivers who may have been tested previously for HIV and as such, these caregivers may not require an intense pre-test information session.

For caregivers who may choose to test their children for HIV using self-tests, being offered pre-test information on HIV may facilitate and enhance informed decision-making by the caregiver of either accepting or refusing to use the self-test on their child (Gardner, 2012). This pre-test session would also educate and provide information about the benefits and risks of undertaking HIVST on the child. It is important to note that the Children's Act (2005) does not explain how counselling should be delivered during HIV testing of a child, which in this case would apply to either the caregiver alone or would include the child with maturity. Also, there are no details provided in the Act on the structure, format, or content of this pre-test information session (Dhai and McQuoid-Mason, 2020).

The introduction of HIVST in South Africa meant that HIV testing moved away from the health facilities, which in itself limited access to the needed traditional pre-test information (Fischer et al., 2023). Generally, depending on the setting, pre-test information could be provided to the client as an individual, in a group setting, through health talks, using short videos, and sometimes by making use of some relevant and appropriate printed material (WHO, 2021).

The WHO Guideline on HIV disclosure counselling for children up to 12 years of age (2011) states that children who are of the same age may not necessarily have the same level of maturity. The same guideline also mentions the importance of assessing the maturity of children when determining how they should be engaged and involved in the decision-making process regarding their HIV testing and disclosure of their HIV results (WHO, 2011). The children's understanding of the information shared with them, and the implications of an HIV test, which would be discussed during the pre-test information session, would vary considerably depending on their

age and maturity (Gyamfi et al., 2017). The closer the children are to the age of HIV consent, which is 12 years of age in South Africa, the more likely they would have some degree of maturity and may need to be engaged more in the decision-making of issues related to their HIV testing, compared with those children who may be much younger (Gyamfi et al., 2017).

The South African National HIV Self-screening (HIVSS) guidelines (2018) state that:

> "All HIVSS kits will have adequate pre-test and post-test information for the user, which will be provided in the product package insert. Additional support can be provided through flyers, a national AIDS helpline, videos, trained HTS providers, and/or smartphone applications. Counselling will be offered to those who present to a trained HTS provider for confirmatory testing after a reactive self-screening test" (National Department of Health, 2018 p.14).

Many authors have recommended that effective HIV pre-test information be delivered either verbally or by using other formats such as printed materials, posters, brochures, and short videos (Cohan et al., 2009; Bell et al., 2015; WHO, 2016; National Department of Health, 2018). There is also a minimum standard of information to be provided before a test, which entails information on the risks and benefits of HIV testing, which then informs and guides the decision-making process related to informed consent obtained from the client (Gardner, 2012).

It is important to emphasize that according to the South African guidelines on HIV self-screening (2016), pre-test information for caregivers who choose to use HIV self-tests to conduct HIV testing on children should, in addition to the minimum standard of information, include a

demonstration on how to use the self-test kit, and this demonstration is usually conducted by the provider when the test kits are issued (National Department of Health, 2016). Studies show that there are tools and platforms available for effective pre-test information that may be used for caregiver-assisted HIV testing of children using self-tests, making it possible to be conducted lawfully (Wang et al., 2017). These tools include digital platforms and the use of printed materials and videos which have been recommended in the various HIV guidelines in South Africa for use in HIVST for decision-making (Wang et al., 2017). These platforms have also incorporated methods of demonstration on the use of self-testing kits.

2.3 Post-test Information in Caregiver-assisted HIV Testing of Children Using Self-tests

By definition, the HIVST refers to a process where users collect their specimen sample, perform the test and interpret the results in a private place of their choice (National Department of Health, 2018). Based on this definition, access to post-test counselling at a health facility for users of HIVST would be difficult. As mentioned earlier in the chapter, the Children's Act has clearly stated that post-test counselling is an essential requirement for HIV testing in children, regardless of the HIV testing approach and the type of test kit used to test the child. Having post-test counselling as an essential requirement for HIV testing implies that for caregiver-assisted HIV testing of children to be lawful when self-tests are used, there should be a demonstration of effective post-test counselling for both the caregiver and the child where appropriate (Children's Act, 2005).

In addition, the WHO has recommended that countries should focus more on the quality and efficiency of HIV counselling, proposing client-centred post-test counselling rather than using an

approach with generalized messages for everyone (WHO, 2015). This recommendation on quality counselling has caused a shift towards a more effective approach that addresses the immediate needs of the client, depending on their final HIV status.

A negative HIVST is regarded as a final diagnosis and does not require any further testing, while a positive HIVST requires a person to be retested by a trained healthcare provider (National Department of Health, 2018). When caregivers use HIV self-tests on children, they may not require any post-test counselling; however, should the child test HIV positive, then post-test counselling for the caregiver would be necessary for supporting the linkage to antiretroviral treatment (ART) and in facilitating disclosure of the HIV status to the child, where appropriate (Mabuto et al., 2020).

Having established the need for post-test counselling, especially when the HIV results are positive, it is important to explore how this post-test counselling could be delivered in the context of HIVST conducted on a child by a caregiver. The key elements of post-test counselling that would be necessary for the caregiver who has tested a child for HIV using a self-test would include support in the interpretation of HIV results, and if positive, determining if partial or full disclosure of the positive HIV status to the child would be appropriate and necessary, and providing support for connecting to further services and the linkage to ART services (Chen et al., 2024).

Two types of post-test counselling have been identified. First, the active post-test counselling that involves proactive initiatives, which in this case would support caregivers after conducting

the test, unless such counselling has been declined (Hameed et al., 2016). Second, passive post-test counselling where caregivers would, on their own, report the result of the HIVST they conducted on the child, which would then trigger post-test counselling and further support (Hameed et al., 2016).

The self-tests that caregivers would use when testing their children for HIV are rapid diagnostic tests, where results could be available within a few minutes to the caregiver in their home. These rapid results might not be tracked back to the health facility which could offer a more structured post-test counselling and linkage to services and care (Fischer et al., 2023). To mitigate this limited support from health facilities, various smartphone applications have been developed to support self-testers in South Africa by tracking their results and linking them to care, while also assisting them to self-report the outcome of their HIV results (Gous et al., 2020; Fischer et al., 2021). These applications have focused on the self-reporting of results by the tester and have been designed to trigger any remote post-test counselling.

2.4 Conclusion

It is clear from the above discussions that pre- and post-test counselling is a requirement for lawful HIV testing of children by caregivers even when they choose to use self-tests. I have demonstrated that HIVST is an approach to HIV testing that has moved testing away from the healthcare facilities, making traditional face-to-face HIV counselling difficult to achieve.

For pre-test information, I mentioned earlier that studies demonstrated that there are various innovative ways of ensuring that pre-test information reaches the caregiver and the child, if

sufficiently matured, before the caregiver conducts the HIV testing on the child using the self-tests, which include: (1) counselling that can be provided by a trained provider when the caregiver is offered or given the self-test, (2) the use of brochures and other printed material, (3) short videos, and, (4) information inside the self-test kit for consumer use (Bell et al., 2015). I also highlighted that even though it is possible to provide pre-test information to the caregiver and the child who has sufficient maturity, the pre-test information only closes existing information gaps, and some caregivers who would use self-tests on their children may decline it if they have tested a few times before. Therefore, it would be wrong for South Africa to make pre-test information a legal requirement for all children who are tested for HIV and that instead, pre-test information should be conditional and be enforced for provision to only those children and caregivers who need it and those who are undergoing an HIV test for the first time.

For post-test counselling that is required for children and caregivers following the use of self-tests, the discussions in this chapter have pointed out that post-test counselling is important and necessary (McQuoid-Mason, 2007; Makusha et al., 2015; WHO, 2016; National Department of Health, 2018). For caregiver-assisted HIV testing of children using self-tests, the post-test counselling would include additional support for age-appropriate disclosure of the positive HIV status to the child, including support for linkages to HIV care and treatment (Mavedzenge, Baggaley and Corbett, 2013). The caregiver would also need to be supported on the stigma and discrimination that the caregiver and the child who tested positive may experience. For those children who test HIV negative, no further intense post-test counselling is necessary for the caregivers, except for breastfeeding caregivers whose children may still be breastfed and would

be at ongoing risk of exposure to HIV. These breastfeeding caregivers would need additional guidance on how they can prevent these children from acquiring HIV infection.

I demonstrated how digital tools could be used to track HIVST results and link users of HIVST to care and treatment. Most of these tools were tested in South Africa (Gous et al., 2020; Fischer et al., 2021; Fischer et al., 2023). Even though these tools seemed effective in tracking results, they have not been demonstrated to be adequate as post-test counselling tools for the caregiver and their children where self-tests have been used to diagnose HIV in these children, because the tools did not incorporate counselling of the caregiver or the child with maturity.

Even though it is possible to comply lawfully with the implementation of the pre-test information when caregivers test children for HIV using self-tests, pre-test counselling should be conditional for those who require it and not be made mandatory for all children. Regarding post-test counselling, the arguments in this chapter show that it is important that all children with maturity and caregivers who test these children using self-tests should have access to post-test counselling, especially when the results are positive for HIV. However, it was also highlighted that post-test counselling should not be confined to face-to-face modalities, but that instead, the legal framework should be revised to accommodate HIVST and allow innovative ways of providing post-test counselling remotely and through interactive digital platforms to be able to comply with the legal requirements.

In the next chapter, I will address ethical concerns to be considered with the provision of comprehensive informed consent for HIV testing and how these ethical issues impact patient autonomy when caregivers test children for HIV using self-test kits.

CHAPTER 3 – INFORMED CONSENT AND CAREGIVER-ASSISTED HIV TESTING IN CHILDREN

Informed consent is generally described as the process where a competent patient is educated by a healthcare provider on the benefits, risks, and alternatives of a specific intervention, where a patient would be in a position to make the decision for or against the proposed intervention voluntarily (Shah et al., 2023). In this chapter, I will explain the legal framework related to informed consent and HIV testing in children in South Africa, while also demonstrating the ethical concerns regarding these legal requirements, especially on HIV self-testing. I will then explore the practicability of conventional informed consent and its application in caregiver-assisted HIV testing of children when they use self-tests.

3.1 Informed Consent and HIV Testing in Children in South Africa

Section 8 of the South African National Health Act (61 of 2003) states that the healthcare user must be afforded the right to engage in decisions that affect his or her health and treatment, which in essence, makes provision for autonomous decision-making (National Health Act, 2003). This is complemented by section 12 of the South African Constitution which emphasizes that by failing to obtain informed consent, the patient's right to bodily integrity as described in the Constitution could be violated (South Africa, 1996).

In South Africa, children who are below the age of 12 years and without sufficient maturity cannot, by law, give consent for any type of HIV testing, and these children depend on their parents or guardians to provide consent on their behalf (Children's Act, 2005). This age restriction means that in the case of HIV testing in children who are below the age of consent and without sufficient maturity, legally, caregivers would have to give informed consent on behalf of these children when they are tested for HIV. According to the National Health Act (2003), caregivers are expected to consent with a full understanding of how HIV testing would be conducted in the children, the benefits of the testing strategy being used, the risks involved, the consequences, and implications of both negative and positive HIV status, as well as information on other testing options available to them (National Health Act, 2003). The caregivers and the children should also be afforded the right to refuse HIV testing.

In addition, informed consent and autonomy are designed to create an opportunity for caregivers and parents to express their preferences freely, while at the same time empowering them to make rational informed decisions about the health of children under their care (Dhai and McQuoid-Mason, 2020). Respect for autonomy as a principle refers to a self-rule where a person who is competent intentionally makes choices without being influenced unduly, and after being made aware of possible benefits and risks of their choices (Motloba, 2018).

The South African National HIV Testing Policy is aligned with the Children's Act, as it also reflects the age at which children can consent to HIV testing independently to be 12 years and

above and with maturity, while allowing someone else to decide to consent for younger children (South Africa, 2015).

As a way of protecting the rights of people who were infected with HIV, the global community in the early years of HIV agreed to adopt HIV exceptionalism, which refers to an exceptional status given to the HIV response (Smith and Whiteside, 2010). The exceptionalism approach to HIV informed how countries designed their HIV policies, including legal requirements such as informed consent, which were meant to mitigate stigma that could discourage people from testing for HIV.

While informed consent is an essential legal requirement for HIV testing in children, the existing legal framework does not differentiate amongst the different types of HIV tests and modalities that may be used in children. There is also a need to determine how informed consent as a legal requirement for HIV testing in children can be applied in caregiver-assisted HIV testing of children using self-tests.

3.2 The Structure and Principle of Informed Consent and HIVST

Maxwell Fry (2024) has highlighted the importance of understanding the relationship between informed consent and voluntary consent. In the case of caregiver-assisted HIV testing of children, voluntary consent implies that caregivers would willingly and freely decide whether they would like to conduct HIV testing on the children without being coerced or pressured to do

so. However, the freedom to make a decision freely may not necessarily mean that the decision is fully informed. When caregivers give informed consent, they would have to be educated on HIV testing and have a good understanding of harms and benefits of the HIVST approach, which would inform their decision-making process (Fry, 2024). It is important that comprehensive consent obtained from the caregivers be both voluntary and informed to be valid.

The autonomy of patients, which has to be considered and respected by healthcare providers, acknowledges the ability of patients to make autonomous decisions and their right to make choices and hold views about their own health based on their value system (Dhai and McQuoid-Mason, 2020). This ethical and fundamental principle underpins the consideration of informed consent in the practice of medicine and provides the necessary information that allows patients to choose what is best for them. The role of obtaining informed consent is to ensure that patients make intelligent decisions about treatment or intervention procedures that are offered to them, which is an essential biomedical and ethical principle (Agozzino et al., 2019). Obtaining informed consent also serves as an important enabler of respect for individual autonomy, making it possible for patients to be autonomous when deciding whether to agree or decline to consent to certain interventions.

Jonathan Pugh (2020), in his book, *Autonomy, Rationality, and Contemporary Bioethics*, when defining the structure and limits of informed consent, describes this concept by using the scenario of a healthcare worker who needs to perform some intervention on a patient in whom they do not have a moral right to intervene. Pugh explains that the healthcare worker would

morally need to obtain informed consent from the patient before conducting the intervention on the patient (Pugh, 2020). For this consent to be given, the patient has to be provided with information by the healthcare provider and has to understand the details of the intervention and the possible consequences, both good and bad, to be able to make an intelligent decision as to whether to agree that the healthcare provider could perform the intervention on them. The information that explains the planned intervention provided by the healthcare provider allows the patient to make the decision that would permit the healthcare provider to conduct this intervention, and this permission is the informed consent (Pugh, 2020).

In the context of HIV testing in general, according to Pugh (2020), the informed consent process would mean that the patient may have a claim against the healthcare worker if they conduct HIV testing without their informed consent. In other words, the right of the patient to bodily integrity would need protection from a healthcare provider who is testing them for HIV. However, when the patient gives informed consent, in essence, they waive their rights of protection and any claims against violation of their bodily integrity. Without this consent, it means that the rights of patients are still at play when they are tested for HIV and not waived and would be violated by this intervention (Pugh, 2020).

This description of the structure of informed consent makes sense when applied to traditional HIV testing, which in most cases is within a health facility setting, where a healthcare provider would either draw blood from a patient and send it to the laboratory for analysis or may use a rapid diagnostic test on the patient which delivers results within minutes. On the other hand, the

legal framework and guidelines for HIV testing of children in South Africa are premised on the context where there is a doctor or healthcare worker who conducts some intervention on a patient without the moral right to do so. According to Pugh (2020), the patient would have to give consent to waive certain rights that may be violated through this course of action.

The application of Pugh's description of informed consent in the context of HIVST and children requires further exploration. First, with caregiver-assisted HIV testing of children using self-tests, in South Africa, the caregiver or parent is legally permitted to give consent to medical treatment on behalf of a child under their care who is below the age of consent for that particular intervention (Children's Act, 2005). Second, if the caregiver is allowed to test his or her child for HIV using the self-tests, they would be representing the party that does the intervention, which is conducting HIV testing on the child, for which, legally, they would need to obtain informed consent. Third, the caregiver represents the child on whom this action is performed, and is expected to give informed consent on behalf of the child for the intervention that the caregiver himself or herself is going to conduct (Pugh, 2020). The application of Pugh's description of informed consent highlights the dilemma that obtaining informed consent from a caregiver who intends to use a self-test on a child may be more complex and less practical.

Given the understanding that informed consent involves an agreement to waive certain rights by one person that may be violated by another, informed consent in the context of HIVST would require re-thinking (Frith, 2005). The context within which the principle of informed consent has been formulated makes its application in HIVST difficult to incorporate. This argument is based

on the fact that with HIVST, there is no healthcare provider present, and the user is both the patient who receives the service and also the provider of that same service, which makes giving and obtaining informed consent by the same person not practical.

According to Dhai and McQuoid-Mason (2020) to have valid consent in place, four legal and ethical elements need to be met, namely, “Disclosure, understanding, capacity, and voluntariness” (Dhai and McQuoid-Mason, 2020: p.98). It would be easy to apply these elements in traditional HIV testing and one would have to be innovative in considering how these legal elements could still be met in HIVST or how to determine their relevance in the context of HIVST.

To make sense of these four ethical elements in the case of caregiver-assisted HIV testing of children using self-tests, these elements could be incorporated into the pre-test information process, which could be provided through printed material, brief videos, and manufacturer information for use, which may not necessarily and automatically flow into an informed consent process (WHO, 2021). The pretest information sessions, as discussed in the previous chapter, regardless of their format, have to provide sufficient information and disclosure regarding the benefits and risks of the HIV self-test. In addition, the information provided about the HIV self-tests should be in a language and simplicity that matches that of the caregiver, with the understanding that the caregiver is competent enough to understand and make a decision on whether they would proceed with the intervention (Grant, 2021). However, with HIVST, users would have to make that decision on their own without having to consent to anyone. The four

legal elements of informed consent stated above could still be achieved in HIVST through proper delivery of pre-test information. In the context of caregiver-assisted HIV testing of children using self-tests, if these four ethical elements required for informed consent could be achieved through pre-test information sessions, then informed consent as a legal requirement for HIV testing, including HIVST, could be redundant and unnecessary, and should not be made mandatory.

In 2019, the World Health Organization published the Consolidated Guideline on Self-Care Interventions for Health, which defined self-care as: "The ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health-care provider" (WHO, 2019: p.8). This definition of self-care includes the provision of care to dependent persons by their caregivers. The guideline further states that people should be empowered through education to make decisions and be able to enact them independently. It is clear from this definition of self-care that caregiver testing of children using self-tests is a form of self-care. In addition, caregiver-assisted HIV testing of children could be seen as a process that empowers caregivers to address health issues within their families regardless of whether there is a healthcare provider's support and also comprises a process that promotes self-efficacy and autonomy (WHO, 2019). If HIVST is regarded to be part of self-care, then the informed consent related to HIVST, including its application in caregiver-assisted HIV testing of children, would require reconsideration.

3.3 Informed Consent and Case Law

Many legal cases have addressed the issue of consent and patient autonomy, and most of the landmark cases fall under two categories. I will explain these two categories and demonstrate their relevance to the caregiver-assisted HIV testing of children using self-tests.

I refer to the first category as the absence of informed consent, where the doctor proceeded with an intervention and violated the patient's right to bodily integrity. In most cases, the doctor would later be sued because the patient had not waived his or her right to bodily integrity. An example would be the case of *Schloendorff v. Society of New York Hospital* (1914), where Mary Schloendorff successfully sued a hospital for complications she suffered after doctors removed a uterine tumor without her consent, and the judge used the concept of self-determination to convey the importance of obtaining consent from patients (Schloendorff v. Society of New York Hospital, 1914). However, the application of this category of law cases cannot be used in the context of informed consent for HIVST and would not apply to the caregiver-assisted HIV testing of children using self-tests, because, as stated earlier in this chapter, it is practically not possible for the caregiver to offer consent and accept the same consent for an intervention that they would perform.

The second category of cases are those that involve circumstances where consent had been obtained from the patient, but later the courts decided that the doctor had not provided sufficient information to the patient on the potential harms of a procedure or a drug, which invalidated the

consent as it was not fully informed. Five landmark cases related to this category of case law and its application of informed consent are discussed.

The first case is that of *Salgo v. Leland Stanford Jr., University Board of Trustees,* which involved Martin Salgo, who had aortography that left him paralyzed and claimed he was never made aware of the risks associated with undergoing the surgical procedure. The court ruled in his favor for the failure of doctors to disclose to the patient important information, and this case became the landmark for informed consent globally (Salgo V Leland Stanford Jr. Univ. Bd. Trustees, 1957). The second example is the 1972 case of *Cobbs v. Grant,* where Cobbs, who underwent surgery for a stomach ulcer, successfully sued his surgeon, Dr Dudley Grant, for not fully disclosing the risks associated with the operation he performed on Cobbs, resulting in the unintended removal of some of Cobbs's organs (Edwin, 2008). This patient's consent was also not fully informed.

The third case is that of Dr Conrad Murray, who was found guilty of the death of Michael Jackson for various forms of negligence, including treating him with propofol at his request, which later resulted in his death. The case demonstrated that respecting patient autonomy and obtaining consent for interventions without evidence of having educated the patient of the risks involved do not constitute a valid fully informed consent; instead, this type of consent was seen as simply a voluntary consent (McQuoid-Mason, 2012). Dr Murray's case is similar to a South African case of *Castell v De Greef,* which involved a doctor who was successfully sued for not informing the patient about the details of material risks and possible complications of the surgery

he performed. Even though the patient had consented to the surgery, it was not a fully informed decision (Castell v De Greef, 1994). The last landmark case is that of *Esterhuizen v. Administrator Transvaal*, which relates to a 10-year-old girl with a cancerous tumor whose parents successfully sued a hospital after the child suffered complications, where they had consented to mild radiation treatment, but the doctors later gave the child a more aggressive form of radiation without obtaining additional consent for it (Esterhuizen v Administrator, 1957).

In all these legal cases, informed consent has been defined in the context of an intervention conducted by a healthcare provider to a patient, and that this context has shaped the legal framework on informed consent in South Africa. In addition, there are no documented legal cases that deal with informed consent and HIVST, which can show how consent could be obtained in the context of HIV self-testing, where the person who will do the intervention on themselves is the same person who should give consent to waive the right to bodily integrity. Therefore, the absence of such case law implies that one cannot turn to legal cases to establish how to deal with the legal requirement of informed consent for caregiver-assisted HIV testing of children using self-tests.

3.4 Conclusion

I have discussed the legal framework in South Africa related to HIV testing in children, including relevant policies, which demonstrated that informed consent is a legal requirement for HIV testing in children, regardless of the type of testing and the setting where it is delivered. I

then described the structure of informed consent, showing that traditional HIV testing is in the context of a patient and a healthcare worker who provides some intervention for which he or she has to obtain consent, and the patient whose rights may be violated by this intervention and would need to give consent to waive these rights. I highlighted that informed consent in this form and structure is not relevant to HIVST and cannot be applied in caregiver-assisted HIV testing of children using self-testing kits. I demonstrated that key landmark cases in law, both locally and internationally, base their arguments on this basic structure of informed consent. Therefore we cannot rely on these law cases when determining how the legal requirement of informed consent in caregiver-assisted HIV testing of children could be achieved. I also discussed four key elements that are contained in valid informed consent and showed that these elements can still be achieved in caregiver-assisted HIV testing in children using self-tests, without obtaining any informed consent.

It is clear from the discussions in this chapter that it is neither practical nor possible to obtain informed consent in the context of HIV self-testing, including caregiver-assisted testing of their children, and that if HIVST is regarded as part of self-care, then informed consent is not necessary and should be removed as a legal requirement for HIVST in general. Respecting the autonomy of the caregiver and allowing them to make independent decisions related to the use of HIV self-tests on their children may still occur without informed consent (McQuoid-Mason, 2012).

In the next chapter, I will explain the application of the principle of the child's best interests when caregivers conduct HIV testing in children using self-testing kits. I will also explore how the legal framework can be used to determine whether caregiver-assisted HIV testing of children using self-tests would be in the child's best interests.

CHAPTER 4 – THE CHILD'S BEST INTERESTS AND CAREGIVER-ASSISTED HIV TESTING OF CHILDREN

The United Nations Convention on the Rights of the Child (CRC) is a treaty that was adopted in 1989 by countries worldwide, and it encompassed the rights and needs specific to children. The CRC identified four key principles related to children, which were: (1) non-discrimination against the child; (2) the best interests of the child; (3) the right of the child to life, survival and development; and, (4) the freedom of children to have their views heard (UNICEF, 1989). In this chapter, I will describe the standards associated with the principle of the best interests of the child and explore the application of these standards in determining whether caregiver-assisted HIV testing of children using self-tests would be in the child's best interests.

South Africa's Children's Act (38 of 2005) has listed critical elements which constitute a legal framework for testing children for HIV in this country, which are aligned with the CRC recommendations. One of these elements is that the HIV test conducted on a child must be in the child's best interests (Van Rooyen, Strode and Slack, 2016). This principle of the child's best interests applies to all types of HIV testing in children, which would also include the use of HIV self-tests on children. Beneficence and non-maleficence are important principles when deciding on whether it is ethically right or wrong to use a specific intervention and also in determining the best interests of children (Varkey, 2021). Non-maleficence, as a principle, is about not doing harm through the acts of both omission and commission (Graham et al., 2013). When applied to children, non-maleficence implies that children should be protected from interventions that can potentially cause harm, while at the same time ensuring that these children are not harmed

through the denial of interventions from which they could benefit significantly. The beneficence principle on the other hand, entails those interventions which promote the rights and overall good or well-being of children, which also have positive benefits as outcomes (Graham et al., 2013). It is therefore to consider both beneficence and non-maleficence together in the caregiver-assisted HIV testing of children using self-tests when assessing which actions would be in the children's best interests.

4.1 Understanding the Child's Best Interests

Beauchamp and Childress, in their book, *The Principles of Biomedical Ethics*, have referred to the best interests of the child as a standard of making decisions and choosing what is best in issues that affect children (Beauchamp and Childress, 2019). When applying this standard of the best interests of the child to the case of caregiver-assisted HIV testing, the caregiver would be referred to as the surrogate decision-maker. According to Beauchamp and Childress (2019), the caregiver would also have the responsibility of establishing which option could yield the highest gain amongst available HIV testing options for children, while at the same time also discounting the inherent risks of each HIV testing option. Therefore, it would be a mistake to rely solely on the concept of highest gain yield when establishing whether caregiver-assisted HIV testing of children using self-tests is in the child's best interests, because sometimes huge gains in health interventions may still be achieved even when the rights of children have been violated. For example, a child with sufficient maturity may refuse a medical intervention and the child's refusal may be overridden by the caregiver based on the caregiver's belief that such an intervention is in the child's best interests. Proceeding with the intervention on the child should

be done with a proper balance that prevents violation of the child's rights, while at the same time taking into consideration the child's best interests.

The CRC emphasises that the activities and interventions which are related to children, and their best interests should always be the key and primary consideration. In addition, the CRC highlights the importance of treating children as individuals with rights and as human beings and not simply objects under the control of adults or parents (UNICEF, 1989). Even though the principle of the best interests of the child is presented as the fundamental message of the Convention and could have a positive effect on the areas covered by the principle of the child's best interests, the CRC does not define or give clear guidance on how these best interests of children could be assessed. Instead, the CRC left the decision of determining or assessing the child's best interests to the courts, institutions and individuals dealing with children.

The CRC describes three different dimensions of the child's best interests (März, 2022). First, the child's best interests constitute a substantive right, which is a right for the child's best interests to be considered in all the decisions that affect the child. Second, the child's best interests constitute a fundamental legal principle, which is a dimension that ensures that all health-related policies and laws are applied and interpreted according to the child's best interests' principle. Third, the child's best interests constitute a rule of procedure, where the determination of the best interests of a child is integrated into critical decision-making processes related to children (März, 2022).

The application of these three dimensions of the child's best interests in caregiver-assisted HIV testing of children challenges caregivers to ensure that their decision to test children for HIV, and the decision to select a specific approach to testing, would need to be based on the child's best interests as a substantial right of a child, which in this case would be a non-negotiable consideration for caregivers planning to test the children under their care (März, 2022).

In the previous chapters, the HIV testing guidelines and policies, as well as the Children's Act, have all reflected the child's best interests as paramount in HIV testing in South Africa. The HIV policies and laws constitute a sound legal framework from which the interpretation and application of the child's best interests could be derived when assessing the caregiver-assisted HIV testing of children.

The Children's Act (38 of 2005) has cited the best interests of children as paramount and has drawn some of its argument from the CRC treaty, stating that the best interests should be the children's right to be treated with respect. The Children's Act also supports the child's best interests as a constitutional right of children and in addition, the Act states that everyone who works with children must respect, protect, and promote the rights of the child (Children's Act, 2005). In addition, the Children's Act has specifically mentioned the importance of ensuring that whenever anyone conducts an HIV test on a child, regardless of the approach used, it must always be in that child's best interests.

It is important to note that meeting the legal and clinical requirements for HIV testing is not enough when it comes to children, and that in all situations, one has to determine if conducting such an HIV test on a particular child would be in that child's best interests (HSRC, 2012). In South Africa, some standards are needed for the requirement of the best interests of a child to be met, and these standards have been outlined in the Children's Act (2005). I believe that these standards could be used in establishing whether a health decision such as testing a child for HIV is in his or her best interests. It is also important to note that the decision on whether a health intervention is in the child's best interests is a balance of many factors which, in some cases, may include the opinion of the caregiver and that of a child if the child is older or of sufficient maturity (HSRC, 2012).

The key standards mentioned in the Children's Act (2005) that apply to health decisions affecting children could be summarised as follows: (1) the possible effect and impact that the health decision would have on the child, including protection from harm arising from the decision; (2) the characteristics of a child, including age, background, and maturity level of that child; and (3) the security of the child, both emotional and physical, and any disability and chronic illness (HSRC, 2012). I will focus on the first two standards and explore how they could be applied in caregiver-assisted HIV testing of children using self-tests.

4.2 The Possible Effect Principle as a Standard of the Child's Best Interests

One of the standards stated in the Children's Act for establishing if a health intervention is in the child's best interests is: "The likely effect on the child of any change in the child's circumstances" (Children's Act, 2005: section 7(1)(d)). This standard compels us to explore ways in which conducting HIV testing in children using self-tests could affect the circumstances of children and to determine whether that effect would be in the child's best interests.

It has been stated in previous chapters that the prevention of mother-to-child transmission of HIV (PMTCT) programme in South Africa covers children from birth to 18 months of age, and that post this period, no programme in the country routinely offers HIV testing to HIV-exposed infants and children (Ngandu et al., 2019). There is still no systematic way of identifying children living with HIV who were not diagnosed during the PMTCT programmatic access period, and these undiagnosed children are less likely to seek health care until they are older and, by then, most would have developed an advanced HIV disease (Ngandu et al., 2019). I therefore believe that the existing gap in HIV testing of children who are 18 months of age and older presents a need for finding alternative ways of testing children for HIV which could assist in diagnosing children living with HIV, especially those missed by the routine HIV testing programmes.

Evidence has shown that HIV testing in general is a gateway for individuals to gain access to treatment for HIV and that the use of HIVST in children could further facilitate early case detection of HIV infection in infants and children (Dziva Chikwari et al., 2021). In addition,

HIVST which is usually performed privately, has the potential to improve the uptake of HIV testing among those who are under-tested and who are less likely to go to healthcare facilities, while at the same time helping to overcome barriers and direct costs of conventional testing for the users (Witzel et al., 2020).

The use of HIV self-tests in children by caregivers could be an intervention that contributes towards the uptake of HIV testing in those children who are under-tested, thereby addressing the challenge of suboptimal HIV testing in children. This intervention is supported by evidence that HIVST has the potential to identify and link more individuals to HIV care, especially those who would not have been able to access HIV testing (Jamil et al., 2021). If caregivers are allowed to use HIV self-tests in children, this potential improvement in the uptake of HIV testing in these children could have a positive effect on undiagnosed children living with HIV. With this positive effect of improvement in HIV testing uptake, the caregiver-assisted HIV testing of children could meet the child's best interest standard related to the effect of an intervention on the circumstances of the child.

With early case detection of HIV in infants and children, HIV testing could then lead to early initiation of ART and a significant reduction in child mortality, while also slowing down HIV disease progression (Dziva Chikwari et al., 2021). This clinical benefit of reduction in child mortality amongst children living with HIV could potentially be the main positive impact of caregiver-assisted HIV testing intervention using the HIVST approach. The reduction in child

mortality could also be the primary objective of advocating for caregiver assisted HIV testing using self-tests as an alternative HIV testing approach for infants and children.

Even though HIV-infected infants and children face high disease progression and death when undiagnosed, the reduction in mortality as a clinical benefit of HIV testing is also supported by the evidence that early identification of HIV could potentially reduce HIV progression and mortality by 75% and 76% in infants and children respectively (Violari et al., 2008). The positive effect of mortality reduction would therefore be realised because HIVST is designed to target those who would benefit the most from this type of HIV testing, who would otherwise not test for HIV through conventional approaches (National Department of Health, 2018).

4.3 The Evolving Capacities of a Child and the Child's Best Interests

The characteristics of a child have been identified as a key standard for assessing if a health intervention is in the best interests of a child (Children's Act, 2005). These characteristics include age, background and evolving capacities. Article 5 of the CRC emphasises the fact that children, regardless of how old they are, are rights-holders, and this status exists independent of their parents and guardians (UNICEF, 1989). As children grow, they develop and mature progressively and increasingly become entitled to some level of autonomy, agency, and responsibility in exercising their rights. The adults guiding these children should therefore acknowledge and recognize these evolving capacities of children when assessing the child's best interests (UNICEF, 1989). They should progressively engage the children in decision-making

processes related to their health. In other words, "…As children grow and develop, their capacities evolve, and parents must adjust their direction and guidance to enable their children to exercise increasing agency over their lives" (Varadan, 2019: p.307)

According to UNICEF, the concept of respecting the capacity of children that continues to evolve takes into consideration both the increasing age and the increasing maturity of the child (1989). The principle of evolving capacity of children encourages parents and caregivers to engage their children in decision-making in an age-appropriate manner and to treat each child differently depending on their maturity (Varadan, 2019). The evolving capacities principle would allow children at different ages to gradually influence decisions taken on their behalf by parents and caregivers UNICEF, 1989).

Caregiver-assisted HIV testing of children using self-tests in this study focuses on children aged between 18 months and 12 years, which has a wide age range. Based on this wide age range, it is expected that the characteristics of these children would also vary significantly across the two ends of the age spectrum. Caregivers and parents of children have historically been granted the status of being the primary holders of the children's rights with extensive authority over the children (Tobin, 2015). In addition to this authority granted to caregivers, in the past, childhood was also seen as just a single phase in life across childhood ages, which was fixed and perceived as a universal stage, where a child was stuck without any recognition of growing capacities (Tobin, 2015).

According to Spring (2023), infants and younger children generally show limited maturity and cognitive abilities and would require parents or caregivers to represent their interests. This representation of a child's interests is known to be temporary as children's capacities are expected to evolve, making older children increasingly competent to engage in decisions related to their health, especially as they grow closer to the age of consent and the age of majority. It is therefore important to explore how caregiver-assisted HIV testing of children using self-tests could be conducted in the best interests of a child by recognising as well as taking into consideration the evolving capacities of children.

The South African disclosure guidelines for children and adolescents in the context of HIV, TB and non-communicable diseases (2016a) recognise the difficulties parents and caregivers encounter in disclosing the HIV-positive status of the child to a child who is younger than 10 years old. The caregivers are usually afraid of the emotional impact of disclosure to the child and the fear that the child might tell other people about their HIV-positive status (National Department of Health, 2016a). What also exacerbates the problem is the limited guidance to address these fears and to support the parents and caregivers in the disclosure process in the context of the evolving capacities of the children.

If these same parents and caregivers with HIV disclosure difficulties were to conduct HIV testing in children using self-tests, they could exhibit the same fears when faced with the decision to engage the older children in the discussion related to testing them for HIV, especially because they would also have to disclose the HIV test results to them. From infancy to early and late

childhood, the capacities of children warrant increasing engagement in, and disclosure of HIV-related issues appropriate to the child's age (National Department of Health, 2016a). The current guidelines addressing HIV testing of children do not address the evolving capacities of children and instead, when describing obtaining consent for HIV testing, the guidelines make reference to a child with maturity, without a clear description of what maturity means and how it could be assessed (National Department of Health, 2016).

For caregiver-assisted HIV testing to meet the standards of acknowledging the child's developing abilities, one of the things that the caregiver would have to consider and take into account would be the opinions and ideas of the child as they engage and provide guidance in terms of deciding whether to conduct the HIV test on the child using a self-test (UNICEF, 1989: Article 12). This consideration of the evolving capacities of children has to be adjusted as the children grow, and more weight should be assigned to the children's perspectives as they grow in maturity to allow children to exercise their rights. The weighted approach requires parents and guardians to transition to reminders and advice, and gradually allow children to state their views, while assigning these views greater weight (UNICEF, 1989).

According to the guidance of article 12 of the CRC, when children are subjected to caregiver-assisted HIV testing using self-tests, caregivers would have to afford children with sufficient maturity, and who have views on the matter, the opportunities to voice their views on being tested for HIV as a right. These views of children should be afforded due consideration depending on the maturity and age of the child giving those views (UNICEF, 1989). In other

words, the CRC has made it clear that the assessment of the child's best interests cannot be simply what is considered to be the child's best interests; instead, the consideration of the children's right to have their views heard is an important aspect of the child's best interests, which also reinforces the idea that children are bearers of rights (UNICEF, 1989: Article 9).

4.4 Conclusion

From the discussions above, it is evident that caregiver-assisted HIV testing of children could have a positive effect on the suboptimal HIV testing in children, and as such could meet the child's best interests standard of positive effect on the child's circumstances. Determining the positive effect would in addition benefit from the application of beneficence and non-maleficence principles. It has been highlighted that HIV testing of the children would have to be provided in a manner that considers the characteristics of the child such as the evolving capacities of the child, which should be considered on a case-by-case basis, as they would vary based on the age and maturity of the child. There is currently no clear guidance from the legal framework on how age-appropriate views of the child could be considered in decision-making for health interventions affecting children. In this study, determining the children's views regarding being tested for HIV by the caregiver and the choice of the test would be difficult to establish. Without a clear systematic way of gaining access to the child's opinion as they evolve in their capacity, it may be difficult to be confident that the caregiver-assisted HIV testing could meet the standard of consideration of the evolving capacities of children as the child's best interests. Further research is needed to provide more guidance on how age-appropriate views of children could be determined when considering the evolving capacities of children.

CHAPTER 5 – JUSTICE AND FAIRNESS

In the previous chapters, I mentioned the four moral bioethical principles, justice, respect for autonomy, non-maleficence and beneficence, as described by philosophers Beauchamp and Childress (2019). This chapter will focus on the concept of justice as fairness.

The principle of justice has been described as an equitable and fair treatment of persons, treating those that are alike equally, while distributing benefits and risks equitably (Varkey, 2021). It is, however, not clear whether caregiver-assisted HIV testing of children by caregivers, using self-tests, would be a fair and just process, with equitable access to HIV testing for the children. In this chapter, I will start by describing justice through the lens of various philosophers and draw from their theories and arguments for the study. I will then discuss in detail the concept of justice as fairness and its implications for determining the rightness or wrongness of the practice of caregiver HIV testing of children using self-tests. I will conclude by summarizing the views captured in this chapter and what they mean for this study.

5.1 The Principle of Justice

5.1.1 Justice and Utilitarianism

Utilitarian philosophers, Jeremy Bentham and John Stuart Mill, believed in the greatest happiness principle, which holds that the wrongness or rightness of chosen actions is determined by whether the action will result in maximum happiness, while simultaneously bringing less pain to most people (Tseng and Wang, 2021). Utilitarians regard both actions and inactions that harm more people to be morally wrong, even when they are good for a few people. Both philosophers

refer to those actions and inactions that are good for many people, while causing harm to only a few, as morally right, regardless of whether these actions or inactions are just or not (Savulescu, Persson and Wilkinson, 2020).

Evidence has shown that the current rate of HIV testing in children is suboptimal and that poor access to HIV testing in South Africa prevents some children from accessing life-saving ART (UNAIDS, 2022). In support of the use of self-tests by caregivers for testing children, utilitarians may argue that this approach to testing using self-tests could result in overall happiness for many children. This overall happiness could be achieved through the expanded reach of HIV testing and improved HIV case finding, leading to increased access to life-saving ART for many. The utilitarians may further claim that this overall benefit or aggregate good of increased access to ART as a result of HIV self-testing of children by their caregivers could result in a reduction in paediatric morbidity and mortality (Newell et al., 2016).

Allowing caregivers to test children for HIV by using self-tests can potentially maximize utility and lead to greater good for many (Newell et al., 2016). However, John Rawls (1971) highlights the limitations of this utilitarian approach, stating that while striving to maximize utility to achieve the greatest happiness for the majority, such actions would not prevent simultaneous unjust actions that could harm the minority. Rawls further suggests that achieving maximum happiness cannot guarantee that there would be equality and respect for dignity for those in the minority (Rawls, 1971).

It would be a mistake to appeal to the philosophy of maximum utility when deciding on the moral rightness or wrongness of caregiver-testing of children using HIV self-tests because this approach is too simplistic. The simplicity of maximum utility is evidenced by the fact that this philosophy misses the crucial understanding that justice should be applied independently of maximum utility. The two ideas of maximum utility and justice may sometimes conflict with each other, such as in instances where unjust actions or inactions result in maximum happiness, yet these actions would still be deemed to be morally right by consequentialists (Waldron, 2003). This potential conflict therefore implies that the utilitarian theory cannot be used to justify the introduction of HIV testing in children by caregivers using self-tests, because the principle of greatest happiness is inadequate as a basis for a just process of promoting this additional HIV testing strategy in children. The limitation of utilitarianism is based on the fact that justice should override any greater collective good that conflicts with justice itself (Savulescu, Persson and Wilkinson, 2020).

5.1.2 Justice and the Right of Inviolability

John Rawls, in his book, *A Theory of Justice*, states that there is a moral imperative compelling individual to perform their duty, and he refers to this higher moral absolute as justice (McKay, Murray and MacIntyre, 2012). Rawls asserts that every individual possesses a status that makes it impermissible to violate or cause harm to that individual, which he describes as inviolability. He also claims that this individual right of inviolability is founded on the principle of justice (Rawls, 1999). Society, as well as social institutions such as health care systems, would be unjust if they were to override this right of inviolability of the members they serve, regardless of how

orderly and efficient their systems may be. In his book, John Rawls explains this concept as follows:

> "A theory however elegant and economical must be rejected or revised if it is untrue; likewise, laws and institutions no matter how efficient and well-arranged must be reformed or abolished if they are unjust*"* (Rawls, 1999: p.3).

This statement implies that even if scientific evidence shows that HIV testing in children by caregivers using a self-test is an alternative testing approach with potentially better outcomes, the scientific community should still reject this intervention if, in the end, the result predicted fails to materialize. In other words, anything promised, such as the intended impact, simplified testing, positive outcomes, and benefits related to this HIV testing approach in children by caregivers using self-tests, should be rejected if it turns out not to be true (Waldron, 2003).

Those who are supportive of this individual right to inviolability as a principle of justice would contend that the success of a social institution, as measured by its efficiency, should not occur at the expense of justice (Waldron, 2003). Similarly, it would be unjust to place the successes of the HIVST approach and its efficiency as the main reason for caregivers to use this testing modality in children without first establishing whether this would be just or not (Waldron, 2003). As stated above, evidence has shown that HIVST is an effective testing approach that can create many efficiencies within HIV testing programmes (World Health Organization, 2019). However, based on the individual right of inviolability discussed above, this evidence of the effectiveness and efficiency of HIVST cannot be submitted as a reason for either accepting or rejecting HIVST

as an intervention that addresses suboptimal HIV testing in children through caregiver-assisted HIV testing before establishing its impact on justice (Rawls, 1999).

Other philosophers, such as Beauchamp and Childress, attempted to address the principle of justice; however, when doing so, they did not provide a framework that would be useful in helping people determine if their actions were just or not (The Ethics Centre, 2017). Instead, they described various existing theories and contended that distributive justice would be determined by the theory to which people choose to subscribe. This absence of a framework on justice renders their views on the subject of justice inadequate in assisting individuals when deciding what is a morally right choice (The Ethics Centre, 2017).

5.2 Justice as Fairness

5.2.1 Describing Justice as Fairness

Again, according to John Rawls (1971), the principle of justice is based on the concept of fairness. Justice as fairness has been described as an essential element of all social institutions and establishes the non-negotiable and inviolable rights of citizens, which they all enjoy equally and which cannot be sacrificed under any circumstances, even if the reason was a collective good of the whole society (Rawls, 1971). In a fair and just society, the greater good, or collective happiness, is not perceived as more deserving of sacrificing the dignity and rights of a single member of the society, which makes liberties of citizens to be both equal and settled. Rawls's theory of justice as fairness emphasizes that individuals are self-interested and have activities that benefit them, and that society should not at any point require that they forfeit their rights to please the collective (Rawls, 1971).

John Rawls discusses justice on an institutional rather than an individual level and presents it as justice as fairness. In his assertion, he emphasizes how a basic structure of society that is just should be organized and how it should distribute key benefits and burdens of social life. Rawls claims that justice should go beyond distribution and that it should ensure that the basic structures of society guarantee protection against the violation of the rights of members of society (Rawls, 1999).

5.2.2 Justice as Fairness and the Legal Framework for HIV in South Africa

South Africa's Children's Act (38 of 2005) has outlined key principles necessary for testing children for HIV, which include the best interests of children, counselling, obtaining consent, and maintaining confidentiality (Van Rooyen, Strode and Slack, 2016). The South African Constitution, on the other hand, addresses the importance of protecting the best interests of children (South African Constitution, 1996). When evaluating the moral rightness or wrongness of HIV testing of children by caregivers using self-tests in South Africa, we can appeal to the provisions of the law and present them as the basis for making such decisions and use them to establish if the principle of justice as fairness has been upheld.

The constitutional rights and dignity of children being tested for HIV are non-negotiable and inviolable rights that should be respected at all times by the social institutions, which in this case would include the healthcare system. This protection of rights is explicitly expressed in the Children's Act (38 of 2005) and articulated as principles guiding HIV testing in children, which include the best interests of the child (Van Rooyen, Strode and Slack, 2016). It is also enshrined

in the South African Constitution, which presents the best interests of the child as critical in all matters related to children (Constitution, 1996). Any form of HIV testing in children in South Africa, regardless of the type of test and who administers the test, which would include caregiver-assisted HIV testing of children using self-tests, has the potential to be executed in a fair and just manner because the Constitution and the legal framework protect the children's fundamental rights from being sacrificed for any greater or collective good of society. These rights act as the pillar of justice that ensures that the majority in society respect the equality and dignity of children who are in minorities (McKay, Murray and MacIntyre, 2012).

Justice as fairness challenges the basic structures of society and forces society to guarantee that people would not be exploited or coerced into accepting claims that are not true, and that when they participate in certain practices, they would be free, and that this right to freedom would be made available to everyone within the same system (Edor, 2020). The 2018 South African national HIV self-screening guidelines promote a rights-based approach to HIV self-testing and state that: "HIV self-screening must always be voluntary and be without any form of coercion*"* (National Department of Health, 2018: p.13). In addition, WHO (2019) emphasizes the importance of informing individuals who are tested for HIV of their right to decline the offer to be tested for HIV. The healthcare system as a basic structure of society promotes the prevention of exploitation by granting recipients of HIV services the freedom to choose whether they want to accept the HIV self-tests when offered, without coercion, which aligns with justice as fairness. This freedom of choice indicates that if caregivers are offered the HIV self-test to administer to children, they have a right to refuse these self-tests. Meanwhile, if the caregivers choose to use HIV self-tests, they would do so voluntarily, and this right to freedom would be available to all

caregivers who use the healthcare system, thus making this process fair and just. This provision in the guidelines also ensures that no children can be exploited through a process where caregivers consent to illegitimate or untrue claims about this HIV testing approach (National Department of Health, 2018).

5.2.3 Justice as Fairness and Inequalities in HIV Testing

For justice to be fair, every individual within a society should have a fair chance of accessing both the benefits and burdens, regardless of their socio-economic status and other known differences (Edor, 2020). Rawls refers to this as the liberty principle, which simply means that for an action to be just and fair, the freedom to participate in that practice is a right that must be available to anyone who is similarly affected and not to a few selected individuals (Edor, 2020).

If caregivers are allowed to test their children for HIV using a self-test kit, there needs to be a way of establishing if other children in a similar position have a fair chance of being tested for HIV through the same testing approach, regardless of their differences, which would comply with the liberty principle and make the process just and fair (Rawls, 1999). Compliance with the liberty principle may be difficult in the context of caregiver-assisted HIV testing because it requires an understanding of the various challenges and needs that present in the lives of these children.

In South Africa, the inequities that can affect children exposed to HIV and their caregivers include food insecurity, unemployment, and lack of water and sanitation (Porter et al., 2015). Mohammed Ghaly (2015), in his book, *Islamic Perspectives on the Principles of Biomedical*

Ethics, points out that even though equality is perceived to be at the centre of justice, there is far more to justice than just equality, especially when considering that some individuals may be treated unjustly while still being treated equally.

The UNAIDS Global AIDS Strategy 2021–2026 introduced an approach for closing gaps that slow down progress towards achieving the 95-95-95 targets and has put inequalities at the centre of the HIV response (UNAIDS, 2021). These targets suggest that by 2025, countries should have 95% of people living with HIV know their HIV status, 95% of those who have been diagnosed with HIV taking ART, and 95% of those on treatment be virally suppressed. According to this strategy, the HIV-related needs of children have shifted from being viewed through the lens of equality to that of equity, suggesting that there are groups of children who are more vulnerable than others in terms of their risk of acquiring HIV, their access to HIV services, which includes testing, and their risk of dying from AIDS (Richter et al., 2009). Based on their vulnerabilities, the liberty principle for children tested for HIV by caregivers using self-tests calls for disproportionate investment that would level things out, and for prioritisation in the allocation of limited resources to support specific interventions that would facilitate better uptake of this practice and the HIV testing approach for vulnerable children (Newell et al., 2016).

The disproportionate investment may be expressed in different ways. The South African government introduced the differentiated service delivery model for HIV testing, which refers to an approach to HIV testing that adapts the services to the different needs and preferences of the recipients of services and acknowledges that there is no one-size-fits-all (National Department of Health, 2019). Differentiated service delivery approach for caregiver HIV testing in children

using self-tests is a form of disproportionate investment that targets specific individuals and prioritizes specific interventions for them, based on their specific needs and vulnerabilities, which contributes to justice as fairness (Kavanagh and Nygren-Krug, 2021).

The HIVST programme in South Africa has been rolled out in most primary healthcare facilities and community-based centres and offered to those aged 18 years and above (National Department of Health, 2018). As stated in the South African National HIV Self-screening Guidelines (2018), the HIV self-screening programme was designed to reach the undertested, underserved, and those who cannot access traditional HIV testing services for several reasons. This age limitation therefore means that only caregivers who are 18 years and older would be able to access HIV self-tests for children under their care, and these tests would be offered through the HIV testing services. Those children whose caregivers are older children who are still younger than 18 years of age, as seen in child-headed households, would be automatically excluded from accessing the HIVST programme, because they would not meet the age limit stated in the HIV screening guidelines (National Department of Health, 2018). According to Edor (2020), quoting Rawls, justice would be realized in this case when every deserving child has a fair chance of being tested for HIV by their caregiver using the self-test. Children who would benefit the most from the use of HIV self-tests by caregivers would include those with caregivers who experience barriers to accessing traditional HIV testing services, which includes children in child-headed households.

At a glance, this age restriction of 18 years that is imposed on those accessing the HIV self-testing may seem to systematically exclude caregivers of some deserving and vulnerable children

who may benefit from being tested by their caregivers and may seem to reflect an unjust and unfair process by presenting an inequality of opportunities rule (Jamnik, 2021). However, the position taken by the healthcare system in South Africa of limiting access to HIV self-test kits to those aged 18 years and above is justified. This justification draws from Rawls's other statements where he mentions that even though fair equality of opportunity may not permit inequalities, there may be exceptions where there is justification for allowing these inequalities, which in this case would be child-headed households (Edor, 2020).

A child-headed household in South Africa is defined as a family unit that has the oldest person aged below 18 years of age (Meintjes et al., 2009). Caregivers in child-headed households younger than 18 years of age may not have sufficient maturity to be able to handle the burden that comes with the results of a positive HIV status of a child under their care if they are allowed to test younger children using self-test kits. Their exclusion, therefore, would benefit both the child and the caregiver, compared to the potential harm of permitting the opportunity of a caregiver under age 18 testing a younger child for HIV using a self-test. In other words, the system treats equals equally, referred to as horizontal equity, while treating the unequals unequally, described as vertical equity (Ghaly, 2015).

5.3 Conclusion

Justice has been described as one of the basic principles of bioethics (Beauchamp and Childress, 2019). I have highlighted the limitations presented by the utilitarian approach to justice, where I pointed out that utilitarianism focuses on maximum happiness, without consideration for justice. I also show that some unjust actions or inactions that may result in maximum good make

utilitarianism inadequate in determining the moral rightness or wrongness of caregiver-assisted HIV testing of children using self-tests. In this chapter, I also explain that the efficiencies resulting from the use of HIV self-testing cannot be used as a reason to justify caregiver-assisted HIV testing of children using self-tests, without first establishing the impact the approach has on justice.

Based on Rawls's theory of justice as fairness, I have shown that in South Africa, the law and the Constitution, including policies and guidelines, protect the fundamental rights of children and prevent coercion from the health system as a basic structure of society. This protection of rights makes it possible for caregivers to exercise justice as fairness when testing children for HIV using self-tests. I mentioned that there is already disproportionate investment through the use of a differentiated HIV testing approach that addresses inequalities and vulnerabilities that exist among children who may benefit from caregiver HIV testing using self-tests, making the intervention potentially just and fair. There are also cases where unequals are treated unequally, such as limited access to HIV self-tests in child-headed households, which indirectly protects those with lesser opportunities.

I wish to conclude the argument that allowing caregivers to conduct HIV testing in children using self-tests in South Africa can be executed in a just and fair process based on the protective legal framework for HIV in South Africa, as well as the disproportionate investment in HIV testing that adapts the service to the different needs and preferences of vulnerable children.

CHAPTER 6 – CONCLUSIONS AND RECOMMENDATIONS

The challenge of suboptimal HIV testing in children in South Africa and low treatment coverage could be addressed by considering caregiver-assisted HIV testing of children using self-tests as an alternative HIV testing method in children to mitigate progression to advanced HIV disease and death. The overall goal of this study was to describe and critically discuss ethico-legal issues related to caregiver-assisted HIV testing in children who are aged 18 months to 12 years using self-tests. In this chapter, I will draw some conclusions and share recommendations based on the findings which have been described in earlier chapters.

The study showed that pre-test counselling mentioned in the Children's Act (2005) is based on the traditional facility-based HIV testing that requires a trained provider to be present and to offer the pre-test information to the caregiver and child. This process makes pre-test counselling difficult to enforce when HIVST is conducted in children by caregivers, which may be done privately away from heath facilities. Despite these restrictive conditions for pre-test counselling, it is still possible to comply lawfully with the implementation of the pre-test information when caregivers test children for HIV using self-tests, by using print material and videos for pre-test information. The study also highlighted that not all caregivers might find the pre-test information necessary, especially when they have previously tested for HIV.

I conclude by recommending that South Africa should review pre-test information as a legal requirement in HIV testing and consider not making it mandatory for all children and caregivers. Instead, the provision of pre-test information should be made optional for those who need it and

should be presented in a flexible approach through diverse platforms to accommodate HIVST. More research needs to be done on the implications of limited or absent pre-test counselling for caregivers and children in the context of HIVST.

From this study, the importance of post-test counselling was highlighted in HIV testing of children regardless of the testing approach used, which includes supporting caregivers with the disclosure of the child's HIV positive status to the child and linkages to HIV care and treatment. It is important to highlight that the benefit of post-test counselling in caregiver-assisted HIV testing of children using self-tests is dependent on the use of virtual platforms and printed material for linkages to further care. It is therefore important for South Africa to fully embrace the use of virtual interventions in HIV testing and to extend their use to HIV testing of children. More studies need to be conducted to identify age-appropriate virtual tools and platforms which could support caregivers and children of different ages during the post-testing period and in addressing an HIV positive status arising from the use of HIV self-tests in children.

Having informed consent as a legal requirement for HIV testing in children in South Africa is a challenge when the HIVST approach is used. HIV self-testing does not fit into Pugh's traditional structure of informed consent, which requires both the patient and the health care provider to be active participants in this process (Pugh, 2020). Therefore, it is not possible for caregivers to provide informed consent when they test children for HIV using self-tests, because they must give the consent on behalf of the child to waive the rights of the child. At the same time, the caregiver must also obtain the same consent as the person who will conduct HIVST on the child.

The absence or paucity of legal cases that have addressed informed consent without basing their arguments on the traditional doctor-patient structure of informed consent makes it difficult to rely on the law when establishing whether the legal requirements for informed consent would have been met or achieved when caregivers test children for HIV using self-tests in South Africa.

Relevant case law related to HIV testing of children by their caregivers using self-testing kits does not yet exist because this HIV testing approach is relatively new globally, but the case law may be developed in the future. This research report is the first ethical and legal analytic review of HIV testing of children by their caregivers using self-test kits in South Africa and other specific legal guidance is not yet available for inclusion in this report.

Based on the findings of the study, it is evident that it is neither practical, nor possible to obtain valid informed consent in the context of HIV self-testing, including the caregiver-assisted testing of children, which requires a trained provider's presence. I therefore recommend that in South Africa, informed consent should be removed as a legal requirement for HIVST in children. In addition, the study demonstrated that HIVST meets the criteria for self-care, which would promote independent decision-making by caregivers for actions related to the use of HIV self-tests in children. For self-care to be realised, this decision-making process may occur without informed consent as part of respect for autonomy.

The study showed that the Children's Act and the HIV guidelines can be relied on for the interpretation of the application of the child's best interests in caregiver-assisted HIV testing of

children using self-tests. Even though caregivers constantly make decisions on what would be best for children while at the same time discounting inherent risks of their choices, establishing the child's best interests when caregivers test children for HIV using self-tests goes beyond simply counting highest gains, and purposefully includes the protection of children's rights.

In the previous chapters, I demonstrated potential clinical benefits of using HIVST in finding undiagnosed children living with HIV, which include linking HIV positive children to life-saving ART. However, there is still lack of clarity on how the views of children would be considered in the decision-making process, taking into consideration the evolving capacities of these children when they are tested for HIV by caregivers using self-tests. This absence of guidance from the legal framework and policies on how age-appropriate views of children could be extracted from the children when health decisions are made means that there is no standardised approach for respecting children's opinions as they evolve in their capacity. Based on these findings, it would be difficult to be confident that the caregiver-assisted HIV testing could meet the standard of consideration of the evolving capacities of children as the child's best interests.

I showed earlier that the application of utilitarianism in determining moral rightness or wrongness of caregiver-assisted HIV testing of children using self-tests is inadequate because of the utilitarian focus on maximum happiness, where unjust actions by the caregiver could be classified as morally right based on the happiness they produce.

In South Africa, it is possible for caregivers to exercise justice and fairness when testing children for HIV because the Constitution and HIV policies protect the fundamental rights of children who are tested for HIV. This protection makes it possible for justice and fairness to be upheld during HIV testing of children without relying on the clinical efficiencies of using self-tests on the children.

Despite all the ethical challenges highlighted in this study regarding caregiver-assisted HIV testing of children using self-tests, South Africa should consider allowing this additional testing approach in children who fall outside the PMTCT programmatic provision age of 18 months and are below the age of consent, which is 12 years. Implementation of caregiver-assisted HIV testing of children using self-tests can still occur while the issues highlighted in this study are addressed and further studies to find certain answers are ongoing. There are adequate provisions currently in the South African law and policies to ensure that HIVST that is caregiver-driven in children is fair and just. These provisions also allow for pre-test information to be obtained through other means such as printed material and videos. More should be done to communicate re-assuring messages that informed consent is not essential in caregiver-assisted HIV testing of children using self-tests, especially when implemented as a self-care intervention. Continuous vigilance in ensuring that HIV testing in children is in their best interests should be emphasised.

The use of HIV self-tests by caregivers in identifying missing undiagnosed children living with HIV would be critical in reducing HIV-related child mortality (Wexter et al., 2020). Findings from this study could play a significant role in informing the decision-making process related to

ethical considerations for HIVST as an alternative HIV testing approach in children, especially when conducted by caregivers.

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