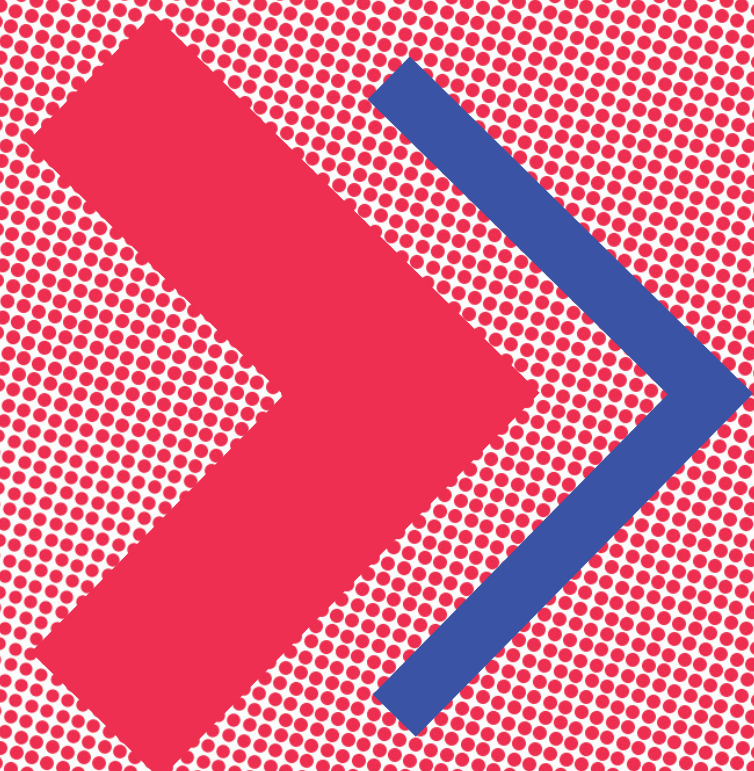
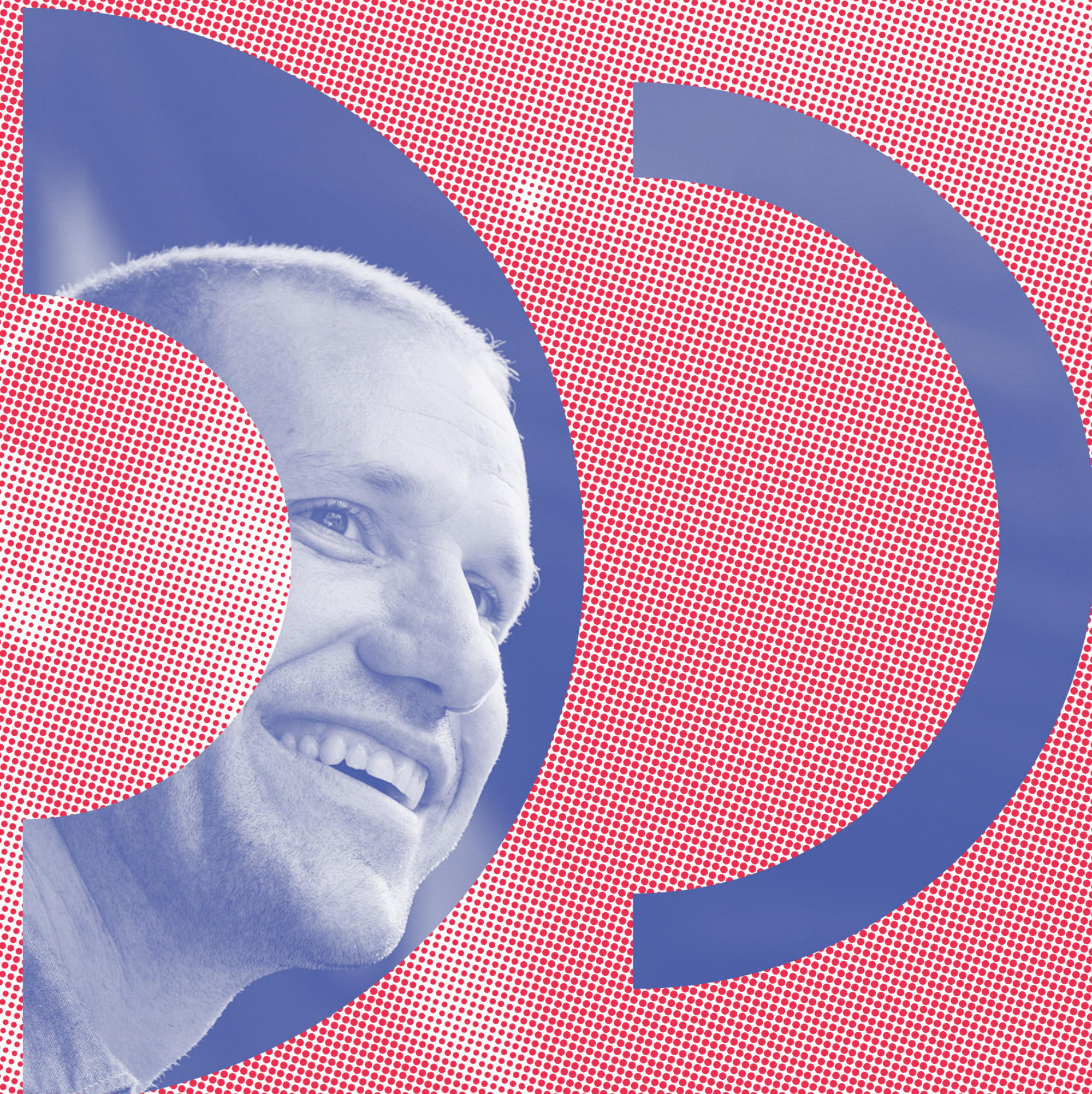


MOVING FOURTH

**A vision towards
achieving healthy
living with HIV beyond
viral suppression**



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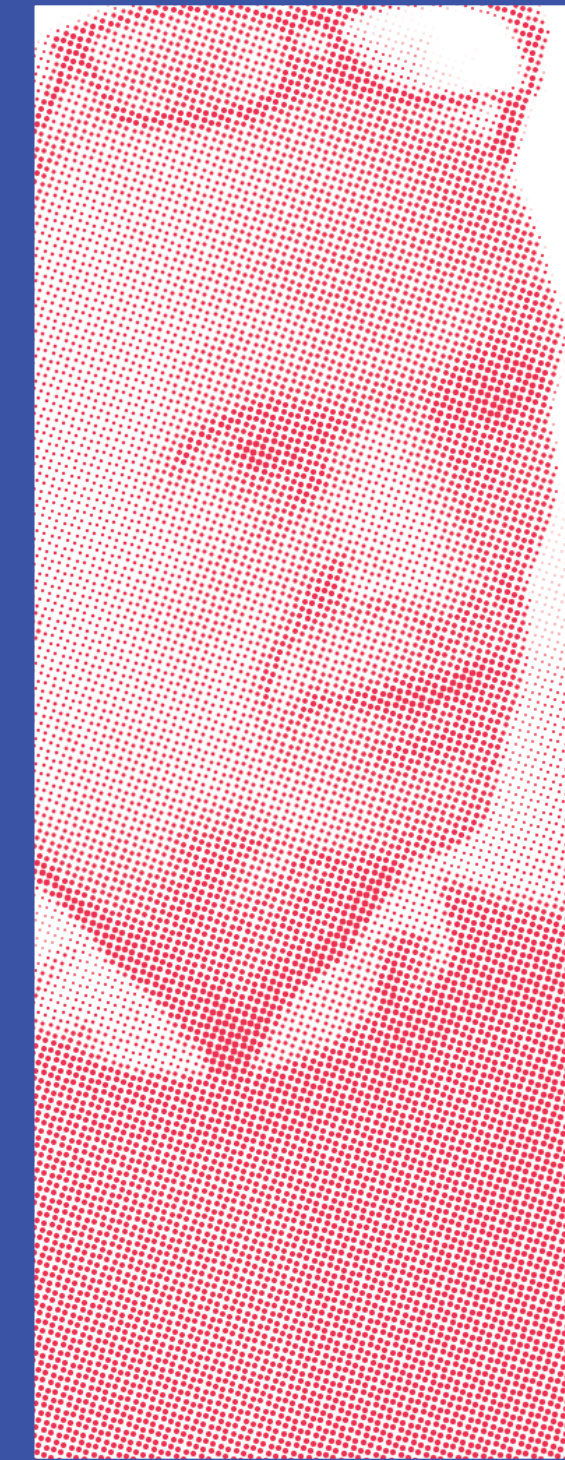
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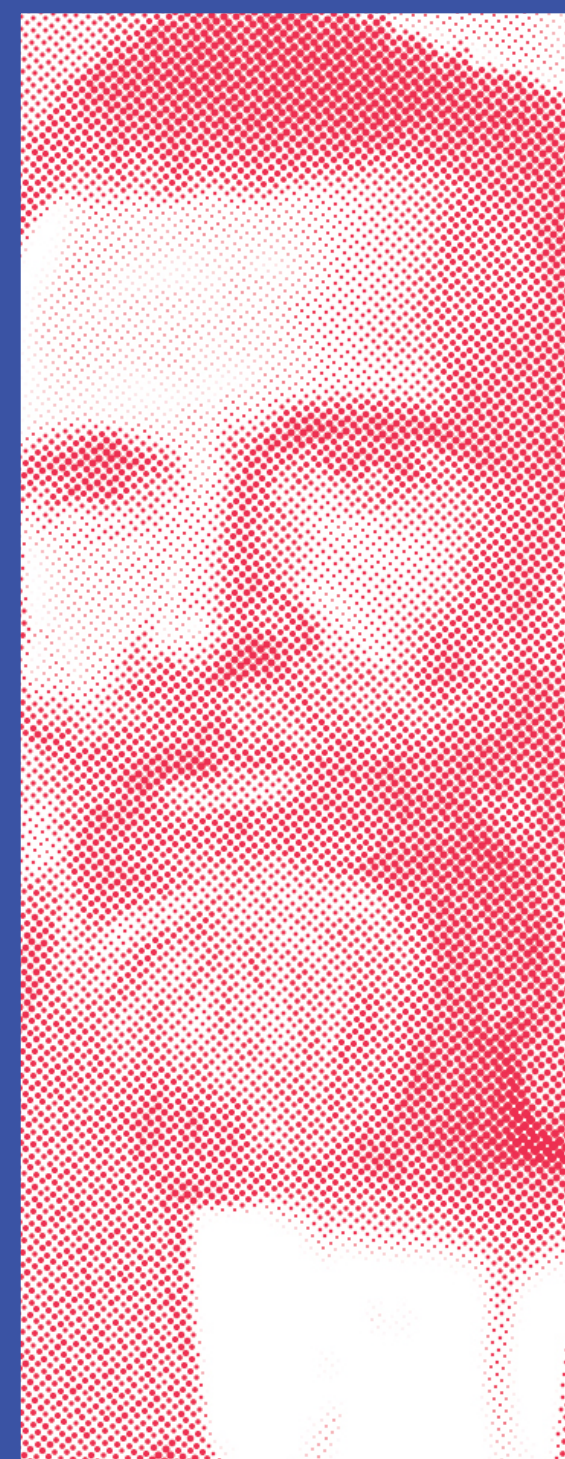
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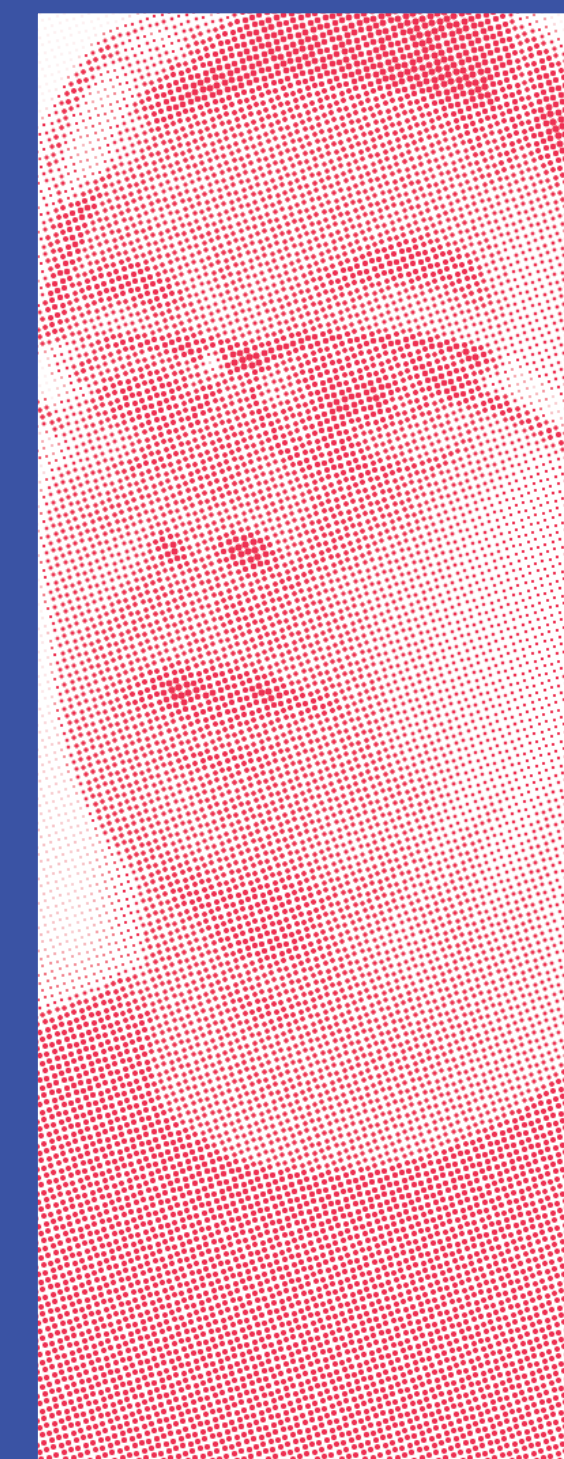
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Christian Verger contributed to the First Chapter of Moving Fourth (2019), however discontinued his efforts with the Steering Committee thereafter and in the subsequent Chapters (2020, 2021).

All information listed on this page regarding the members of the Moving Fourth Steering Committee is correct as of August 2021.



Conflicts of interest

Dr Giovanni Guaraldi reports personal fees and grants from Janssen, ViiV, Gilead, MSD;

Dr Joop Arends reports advisory board fees from Janssen, and ViiV Healthcare;

Dr Thomas Buhk reports advisory board and/or personal fees from for presentations from ViiV, Gilead, Janssen and Galapagos;

Mario Cascio reports personal fees from Janssen and ViiV;

Dr Adrian Curran reports personal fees from Janssen;

Dr Eugenio Teofilo reports advisory board fees from Gilead, Janssen, ViiV and MSD and consultancy fees from ViiV and MSD;

Dr Guido van den Berk has nothing to disclose.

August 2021

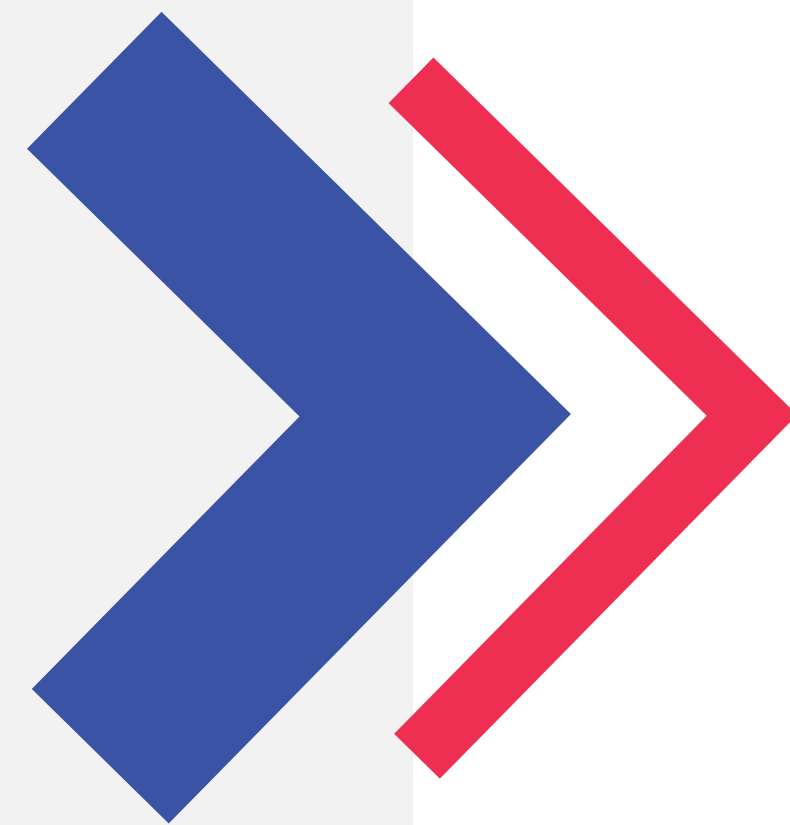


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Executive summary



After years of pioneering research, treatment for HIV has evolved to such a point that HIV is no longer a fatal illness but a chronic condition. This huge accomplishment brings new challenges relating to long-term health, as people with HIV navigate their lives beyond viral suppression. In January 2019, a group of healthcare professionals (HCPs) and patient advocacy group leaders with expertise in HIV formed the Moving Fourth Steering Committee; and met to discuss:

- **The evolving treatment landscape** in HIV
- **The challenges** this evolution poses to the **long-term health** of **people living with HIV** (PLHIV)
- **Potential solutions** to address these challenges
- **Calls to action** to ensure these solutions become an **intrinsic part of HIV care** in the future. these challenges

The concepts presented in this White Paper have been published in AIDS Reviews, a peer-review journal that presents timely and important reviews related to HIV and AIDS.

The published article is available to download at:

<http://www.aidsreviews.com/resumen.php?id=1495&indice=2019213&u=unp>



Introduction

In the past, the objectives of HIV care have largely been the same for all patients: to reduce mortality, improve immunological status and focus on end-of-life care, to reduce the burden of drug-related toxicities, and ultimately, to maintain viral suppression and improve life expectancy.¹ While the universal goal of achieving viral suppression still applies, as the complex HIV treatment landscape and diverse patient population evolve apace, we must recognise that how we reach that goal will very much depend on the individual. Thus, we must adapt how we approach decision-making beyond the goal of suppressing viral load.

In 2016, the World Health Organisation published its ambitious 90-90-90 targets: to diagnose 90% of all HIV-positive persons; provide antiretroviral therapy (ART) to 90% of those diagnosed; and to achieve viral suppression for 90% of those treated by 2020.² Subsequently, Lazarus *et al* proposed the

‘fourth 90’ target, that 90% of people with viral load suppression should have good quality of life (QoL).^{*3} With achievement of the ‘fourth 90’ in mind, the Moving Fourth Steering Committee met to discuss the challenges that face PLHIV who are living beyond viral suppression. They explored ideas to address these issues and made specific recommendations that could ultimately become an intrinsic part of HIV care, supporting the long-term health and well-being of PLHIV.

In this White Paper, the Moving Fourth Steering Committee present its vision for an individualised approach to care for PLHIV – to help achieve the all-important ‘fourth 90’. They report the need to embrace a shift in focus from parameters of HIV ‘disease’ only, towards a bigger picture of ‘health’, which means understanding the objectives of each PLHIV as they face longer life expectancies, and prioritising that which gives value to

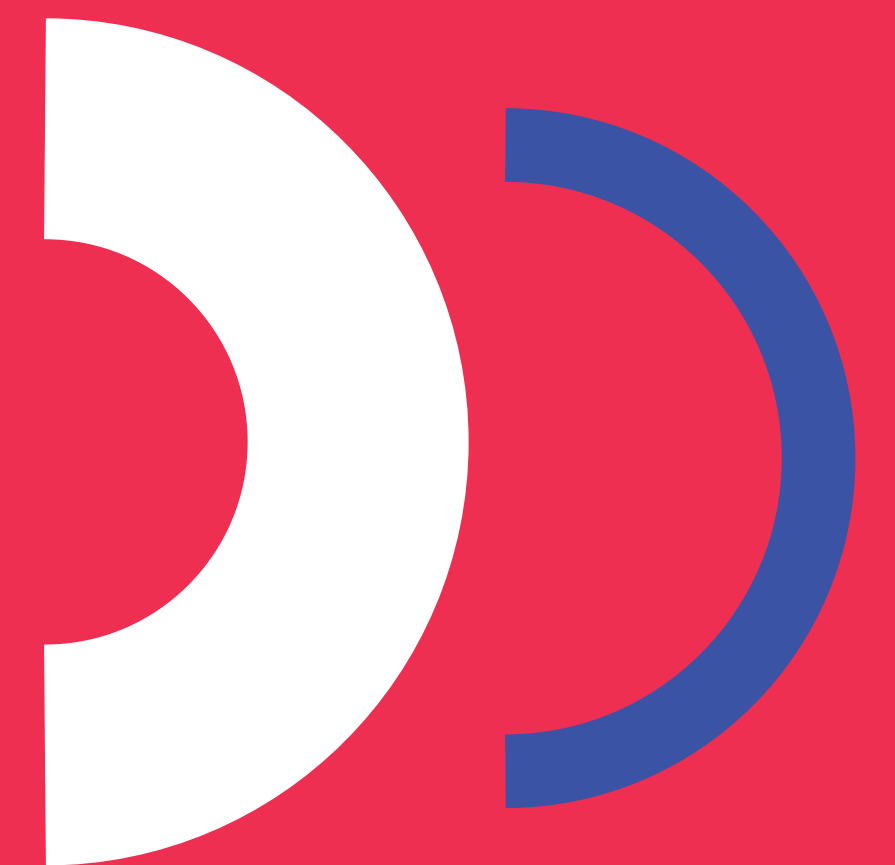
their lives. It means doing this regardless of their socioeconomic status or geography. This Steering Committee envisages a collaborative and proactive approach to assessment of ‘health’ in its broadest sense, and to therapeutic decision-making. The approach would be underpinned by mutual responsibility between HCP and patient, with the goal of reaching long-term healthy living with HIV.



^{*}Since the proposal of the Health Goals for Me framework, this recommendation was updated to include all diagnosed PLHIV, rather than just those who are virologically suppressed.⁴ Furthermore, recently UNAIDs have announced an updated 95-95-95 target to help end the AIDS epidemic. Despite this update, the Moving Fourth Steering Committee believe improving QoL remains a key goal to achieve healthy living with HIV. As such, the framework should still be considered an important component of HIV care.

Evolution in the HIV landscape

In recent years, ART efficacy has increased while disruptive adverse effects have diminished, and treatment regimens have simplified, making adherence easier.^{5,6} As a result of these advancements in HIV management, the life expectancy of PLHIV beyond viral suppression is now close to that of the general population.^{7,8}



Evolution in the HIV landscape

Increasing diversity in the PLHIV population

The Moving Fourth Steering Committee noted that, since more and more people with HIV are virally suppressed and living longer, there is increasing diversity in the patient population. This is not only reflected in the range of comorbidities people experience or the complexity of treatment regimens, but may go far beyond that, concerning age, socioeconomic status, access to medical care, sexuality, experiences of sexual and reproductive health, mental health problems or stigma, and so on.

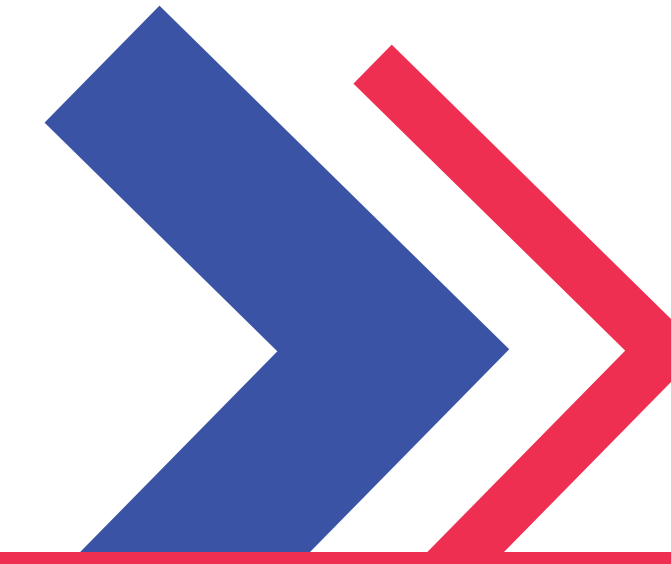
While people naturally experience increased numbers of comorbidities as they age,⁹ ART-experienced PLHIV may have the health status of much older HIV-negative people.¹⁰ While it is possible to live well with HIV in the long-term, there are multiple factors that could impact this:^{11,12} variables of HIV disease

itself; choice of treatment regimen; and the individual's own lifestyle choices could all compromise the possibility of living healthily in the long-term.^{11,12} Moreover, since PLHIV are at an increased risk of some diseases, such as cardiovascular disease, respiratory diseases, and certain cancers,^{13,14,15} and often experience persistent psychological symptoms (including depression and anxiety),¹⁶ they may need to look after their health to an even greater extent than HIV-negative individuals.¹⁷

This Steering Committee report that the management of multimorbidity is vital for – often older – ART-experienced individuals. For younger, ART-naïve patients with a recent HIV diagnosis who face a long life with the disease, both prevention of multimorbidity and consideration of other concerns impacting health are critical. These concerns

may be manifold, including aspects such as HIV disclosure and stigma, sexuality, sexual health, substance abuse, and so forth, and thus will require a collaborative and proactive approach to assessment and treatment.

Evolution in the HIV landscape



Patient versus HCP perspectives

PLHIV often have concerns and priorities that differ from those the HCP might anticipate.^{18,19} A recent qualitative analysis of interviews with patients and healthcare providers demonstrated some disparity in the perceived level of importance of factors influencing decision-making. Obvious differences were observed in the ranking of long-term treatment 'side effects'. While patients named *depression / feeling very sad* as most important, *nausea* and *diarrhoea* topped the ranking for healthcare providers, with *depression* perceived as less important. This survey also showed variable perceptions of the concept of shared decision-making.¹⁹ Thus, there is a need to support HCPs to identify individuals' personal concerns and priorities so that they adequately address the needs of every PLHIV.¹ Moreover, this Steering Committee believes it is important to empower patients to play a part in managing their own long-term healthy lives, as much as they are willing and able.

The availability of increasingly effective treatments for HIV means that, working together, HCPs and patients have new therapeutic choices to make.⁵ While treatment regimens have simplified, the increased risk of comorbidities and accompanying long-term health issues in PLHIV entails an increase of concomitant medication. This is associated with complexity and risks, such as lack of adherence or drug-drug interactions (DDIs).²⁰ Not only that, the Steering Committee reported that living with HIV may lead to discrimination in various aspects of life, including social or professional (making it difficult to get or keep a job; impacting access to credit and insurance, and so forth), which in turn may affect QoL, even when treatments are efficacious. Therefore, the approach to care in HIV must evolve to encompass these variables, whilst ensuring that overall health assessment and therapeutic decision-making are tailored for each patient.

Evolution in the HIV landscape

Societal considerations

Finally, the Steering Committee observed there are great changes taking place in society: political, financial and technological, to name a few – all of which affect healthcare systems. We are working in evolving environments, with ever-increasing restrictions, in terms of resources, finances and consultation time, which may cause fragmentation in care.

This Steering Committee maintains that access should be unconditionally guaranteed for all HIV-positive people, independent of their socioeconomic or legal status. In addition, as some healthcare systems become increasingly digitised, the Steering Committee report that technological advancements should be leveraged to improve efficiency of healthcare provision and ultimately improve the lives of PLHIV, whilst ensuring the critical protection of personal health data.

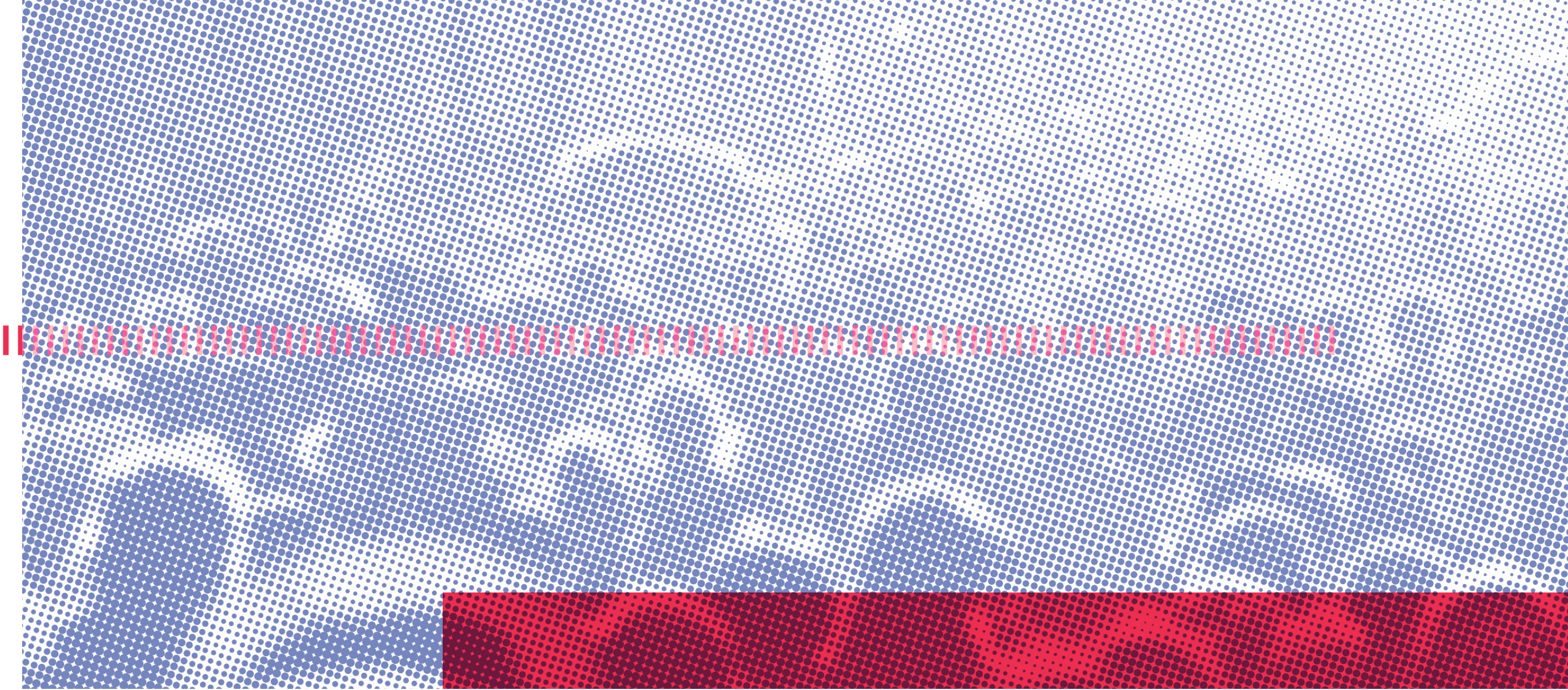


Emerging challenges for long-term healthy living with HIV

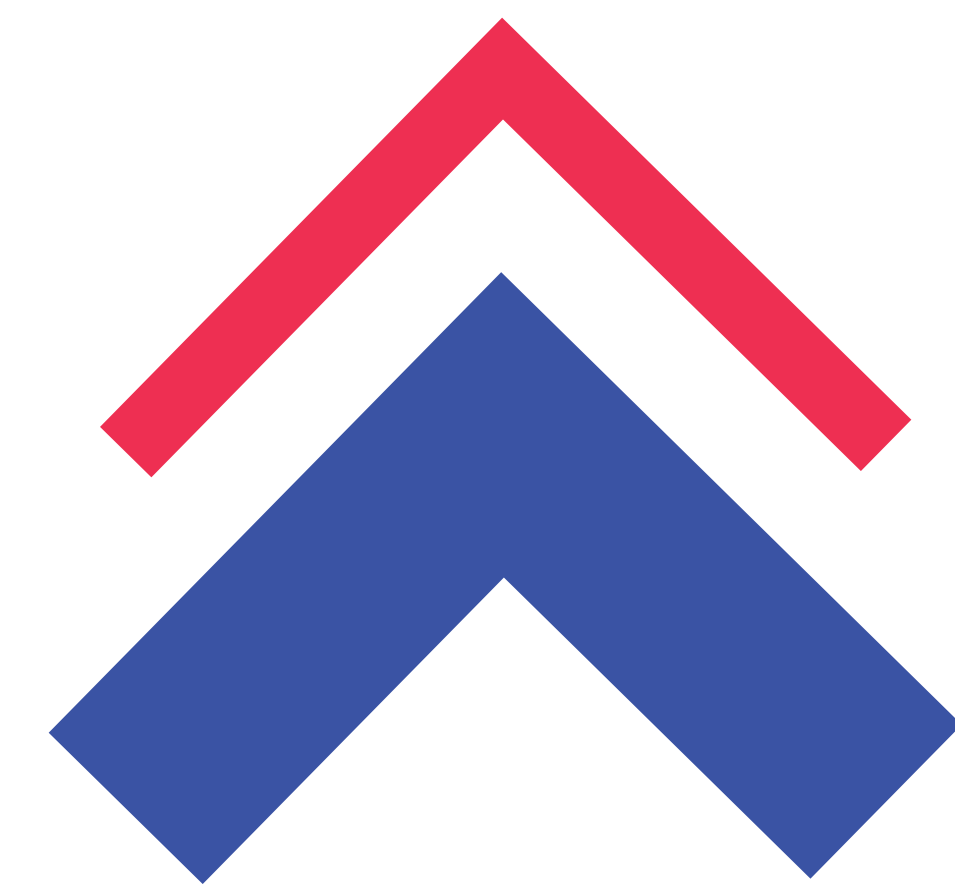
The evolution in the HIV landscape is far-reaching and complex. The Moving Fourth Steering Committee identified what they feel are the greatest challenges for PLHIV beyond viral suppression, and what considerations are necessary to ensure long-term healthy living for these individuals, in the context of this evolving landscape.



Emerging challenges for long-term healthy living with HIV



Treatment guidelines are purely disease-focused, rather than also looking at the bigger picture of 'health', which is required for an individualised approach^{1,21}



Despite improvements in mortality rates, the long-term health of PLHIV beyond viral suppression has not improved at the same rate.²² Still, the emphasis within the treatment guidelines remains the same as 30 years ago: a rightful focus on achieving viral suppression; on management of comorbidities; and on drug-drug interactions.^{1,21} Beyond that, there is little guidance on how to evaluate a patient's QoL and improve upon it where necessary; on management of polypharmacy; on use of technology in HIV care; or on other factors related to well-being, such as sexual health or stigma.^{1,21} This Steering Committee believes that while it is, of course, necessary to carefully address HIV disease in the guidelines, they should not be solely disease-focused. Rather,

they should also address what is needed to achieve healthy living for each PLHIV.

It is critical that the HCP knows what questions to ask to get a full picture of an individual's health status. To note, there is limited guidance in even the latest EACS guidelines about how to ask the patient about their well-being or QoL,¹ although current guidelines do advocate assessing HIV-positive persons' readiness to start and maintain ART. The Moving Fourth Steering Committee note that, in many cases, sub-optimal well-being is regarded as 'normal', and suggested this may be because the right questions have not been asked beyond the somatic disease parameters outlined in the guidelines.

Emerging challenges for long-term healthy living with HIV

Given the evolving healthcare system and the heterogeneity of PLHIV, it is difficult to assess and maintain all aspects of a patient's health status, beyond viral load and CD4+ cell count



To care for an individual living with HIV beyond viral suppression, the HCP requires a good understanding of the diverse issues this population may experience at an earlier age than the general population.²² This Steering Committee suggests ensuring a focus on 'symptoms' and patients' perceived health concerns (i.e. those the patient brings to the table that the HCP would not otherwise know about) rather than on what we might call 'side effects'. Discussion of 'side effects' implies that we think ARTs are responsible. However, in the Steering Committee's experience, it can be difficult to distinguish if an issue is ART-related, or an effect of HIV, or related to comorbidity treatment, or even due to the natural ageing process.

In many cases, multiple HCPs may be involved in managing a person's comorbidities, sexual or reproductive health issues, psychosocial health issues, or experiences with HIV-related stigma.²³ There is a need to determine who will coordinate the treatment plan and how to achieve optimal cross-specialty working, with open channels of communication. Moreover, a balance must be maintained between the need for a multi-dimensional approach to treatment, and the emotional needs of patients who may wish to have one primary HCP to whom they divulge sensitive information.



Emerging challenges for long-term healthy living with HIV

Keeping patients engaged, educated and empowered to adequately manage their own disease

Given the increasingly restricted nature of healthcare systems, in term of resources, finances and consultation time, patients should be encouraged to fully participate in their own treatment plans. Work is needed to support change in their behaviour, so that individuals are engaged, educated and empowered to achieve long-term healthy living with HIV for themselves.

The Steering Committee reported that one important area to explore is that of e-health. At present, there is limited guidance as to the role that digital technology could play in improving long-term healthy living with HIV or about the security of patient data in the digitised environment. Although some initiatives are already available that aim to empower patients to manage aspects of their own care alongside their physicians (e.g. Ageing Smart; or the Happi App www.happiapp.eu for Dutch patients and HCPs), currently there is little consistency,

and approaches vary between and within countries, depending on the individual HCP and local healthcare systems.

The Steering Committee also highlighted an increasing trend towards personal health records being owned by patients either on their mobile phones or stored on computers or credit card chips. With the increasing digitisation of some healthcare systems, personal data protection is a sensitive issue, especially in HIV, where self- and societal stigma may be high. Where physicians require access to patient information, it is important the individual understands why they need it (i.e. avoidance of DDIs) and they are encouraged to share their health information. Ideally, the physician and patient both have access to the information they need for the appropriate purposes; however, the right to see this information will depend on the local healthcare system and the willingness of the individual patient.

Logistical issues may impact patients' long-term health

Representatives of this Steering Committee reported that patients often have their appointments rescheduled or cannot get hold of medication when they need it, which can be disruptive for the success of therapeutic outcomes or family and working life, since individuals need these treatments to be well. Moreover, patients may feel uncomfortable having to speak to new HCPs about what they need.

**So, what is
the solution?**



A vision towards achieving long-term healthy living in HIV

This Steering Committee has a vision towards achieving long-term healthy living for PLHIV. Although life expectancy has improved in many settings, there is still a gap between the overall health status of PLHIV beyond viral suppression and that of the general population.²² However, thanks to advances in ART, we can now use the best available research evidence, clinical expertise and information about each person's circumstances, goals, values and wishes to guide individualised care.^{1,21,24}

This will require a paradigm shift: away from the parameters of HIV 'disease' only, towards a bigger picture of long-term 'health', recognising that long-term healthy living will look different for everyone. This

means understanding the objectives of each PLHIV as they face longer life expectancies, and prioritising that which gives value to each of their lives. It means embracing a collaborative and proactive approach to the assessment of health and to therapeutic decision-making, underpinned by mutual responsibility between HCP and patient, and doing so regardless of socioeconomic status or geography. It means looking beyond the **goal for all**, once viral suppression is achieved, to the **'health goals for me'**.



The ‘Health goals for me’ concept

The Moving Fourth Steering Committee present the ‘health goals for me’ concept (depicted in Figure 1) and supporting framework (Figure 2), an approach that allows each individual to achieve long-term healthy living in HIV, based on what they have reason to value. This is an expansion of the WHO’s concept of ‘healthy ageing’, described as “the

process of developing and maintaining the functional ability that enables well-being into older age”. According to the WHO definition, ‘functional ability’ means each individual being able “to be and to do what they have reason to value”. Although the concept of functional ability is primarily focused on healthy ageing, this Steering Committee

believes it is also applicable to younger patients with HIV, for whom the prevention of multimorbidity and diseases of ageing is critical, and who also experience many social and psychological issues that immediately affect their QoL.

FIGURE 1

Health goals for me*



*Quotations are from members of the Moving Fourth Steering Committee

A vision towards achieving long-term healthy living in HIV

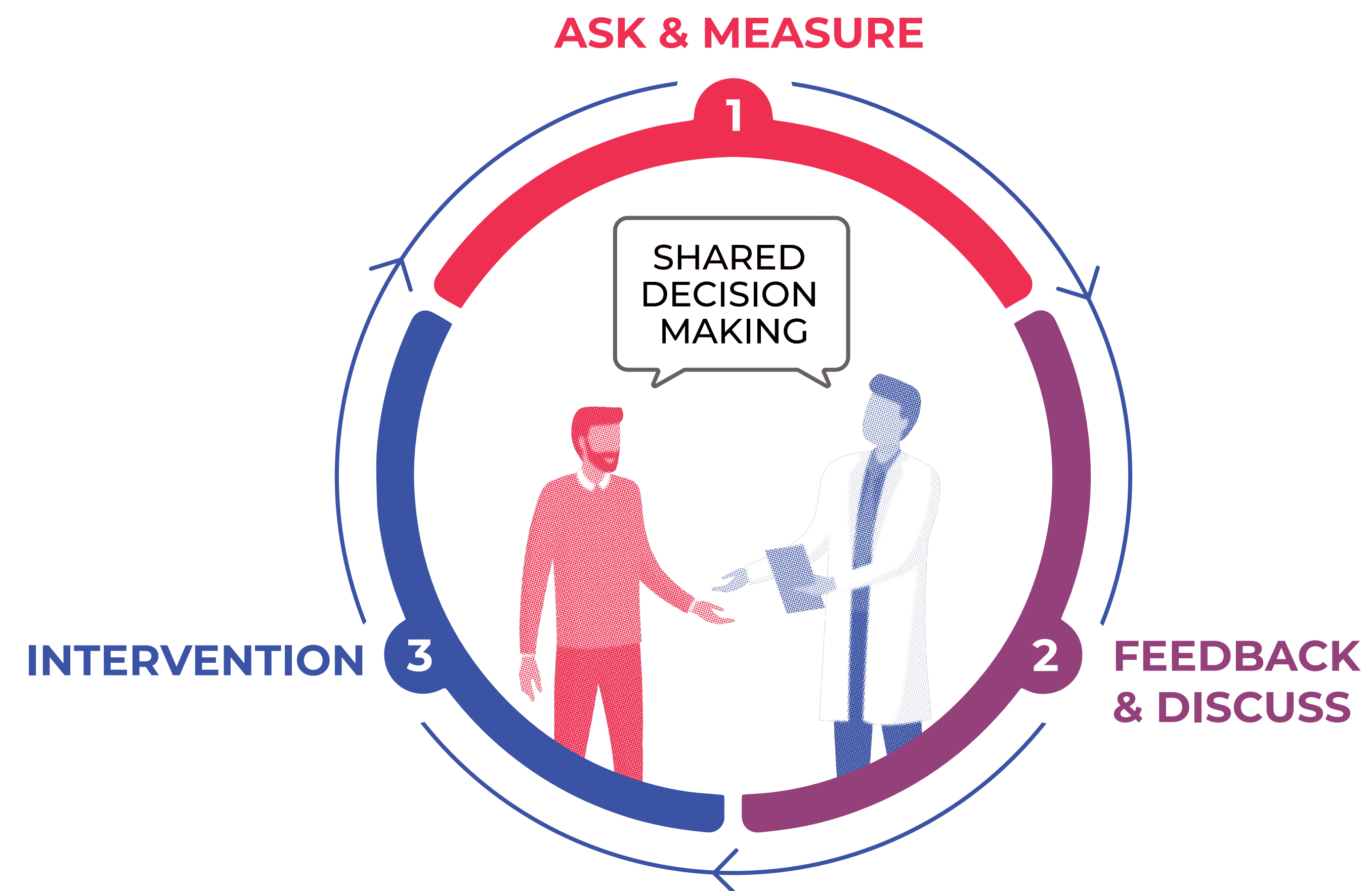
A collaborative and proactive approach to assessment and therapeutic decision-making

We must acknowledge what the PLHIV and the HCP can achieve when working together, as well as what individuals can achieve if they are educated and empowered to manage their own long-term healthy lives, as much as they are willing and able. Thus, the Moving Fourth Steering Committee propose a collaborative and proactive approach to the long-term assessment of HIV, and to therapeutic decision-making, with the aim of identifying individuals' 'health goals for me'. This approach is underpinned by a novel framework (depicted in Figure 2). This framework is designed to facilitate HCPs and patients working together, encouraging shared responsibility, and ensuring that the objectives of both parties are considered in a continuous cycle that follows these steps:

- Ask and measure
- Feedback and discuss
- Intervention

FIGURE 2

Collaborative 'health goals for me' decision-making framework proposed by the Moving Fourth Steering Committee



“The patient is not a doctor, but he is often an expert, and certainly knows what matters most to him or her,”

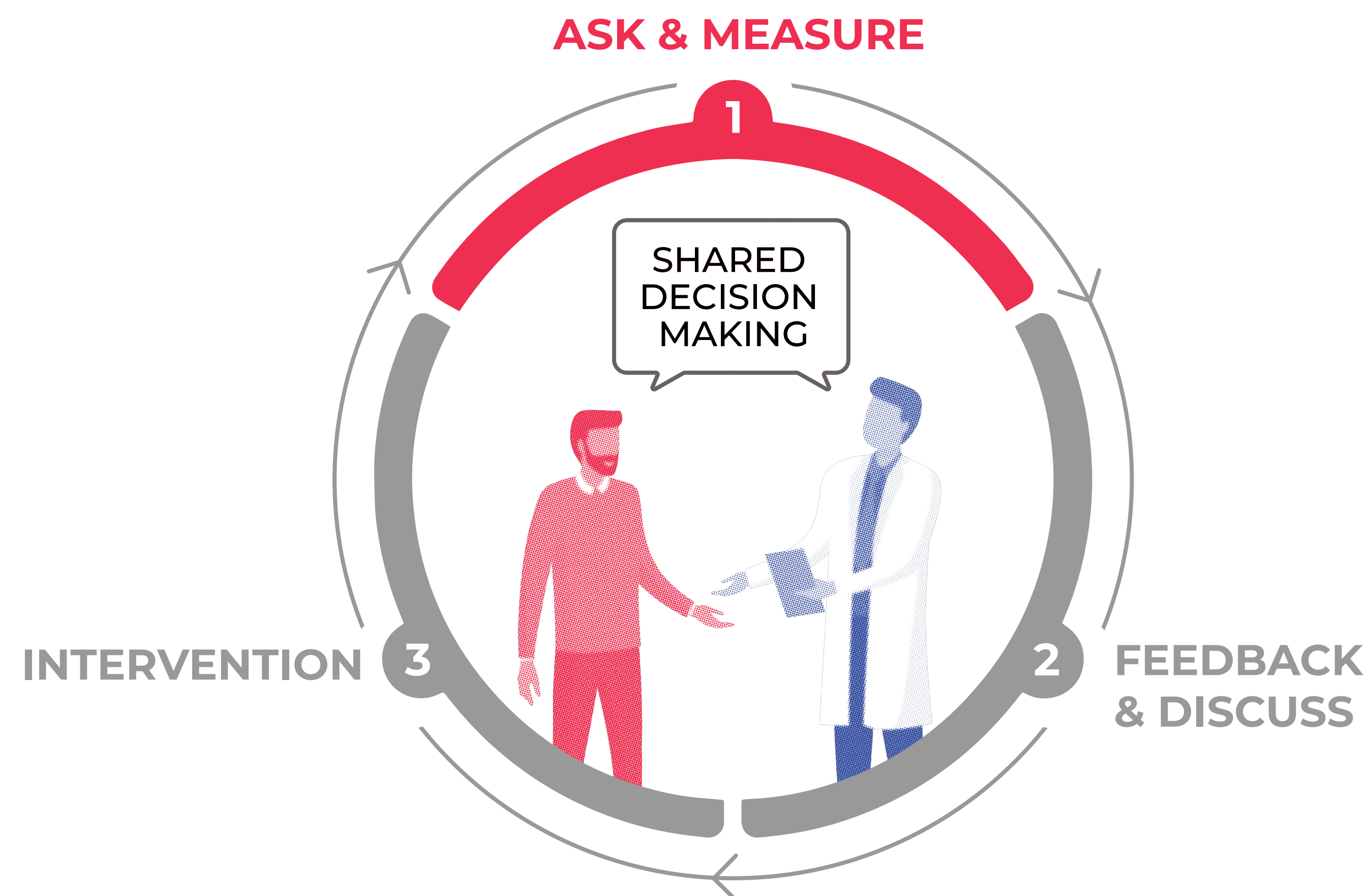
Moving Fourth Steering Committee member

1 Ask and Measure:

asking the right questions and measuring health data

Empower each PLHIV to engage with the management of their long-term healthy living

A proactive approach is required from the HCP to engage the patient. A proactive approach is needed since some patients have many health-related problems, but still highly rate their medication. The Steering Committee reported instances of patients who have been taking the same medications for a very long time, but who are unaware that there may be a problem directly or indirectly related to their current medications. In some cases, patients may not have any problems with their medications, but the HCP must still work to engage that person during the 'ask and measure' phase. It is the responsibility of both parties, the PLHIV and the HCP, to work as a team to uncover and explore the issues that individual may be facing. Levels of engagement will vary depending on the individual; therefore, it is important that flexible and adaptable mechanisms are in place to collect this type of information.





A vision towards achieving long-term healthy living in HIV



Use appropriate questioning

Asking appropriate questions will facilitate the assessment of each PLHIV's health and lead to effective therapeutic decision-making. The aim should be to achieve a clear picture of all symptoms and concerns the person is experiencing at that point in time, of all the medications they are taking, and any other factors that may be impacting their well-being.

A multi-dimensional approach should be taken, proactively asking questions about all aspects of the person's lived experience; not simply 'disease' parameters, their CD4+ cell count and viral load, but also their mental health status, social and sexual relations, experiences of stigma, and so forth, all of which affect the overall picture of health. In some cases, there are validated questionnaires in place to record this type of

information. In other areas, work is needed to ascertain the best outcomes measures to adequately assess the patient's experience and facilitate discussion.

At present, guidelines for assessment and therapeutic decision-making recommend physicians consider patients' preferences or individual lived experiences when choosing an ART regimen, but do not provide sufficient guidance on obtaining and understanding this type of information.^{1,21} Where there are multiple issues to address, PLHIV and HCPs should work together to determine a mutually agreed hierarchy for addressing the patient's needs, with understanding on both sides of how this may impact therapeutic decision-making.



A vision towards achieving long-term healthy living in HIV

PLHIV and HCP both prepare for consultation



Patients should be encouraged to bring information that would otherwise not be available to the HCP (i.e. because they cannot get the information from laboratory tests), with appropriate support to understand what information is useful and why it is needed to create the best treatment plan for them. Such information may include new 'symptoms', medications prescribed by other physicians (both ARTs and other medications), use of over-the-counter medications or supplements, changes in the importance of symptoms as they get older and their situation evolves, or even changes in priority since their last appointment, especially where appointments are infrequent (i.e. perhaps they are increasingly concerned with reproductive or sexual health, or stigma they have recently experienced).

This could be achieved by completion of a pre-consultation questionnaire, with the

potential to explore the role of technology and e-health to facilitate such a process. To note, in an ideal world, as the patient prepares for an appointment, so should the physician, as far as they are able. An HCP who comes to consultations prepared (i.e. having reviewed the individual's responses to any pre-consultation questionnaire) will understand how simple or complex they might expect the consultation to be. They will also be better prepared to ask the most appropriate questions for an individual's personal situation.

Some initiatives are already available that empower patients to manage aspects of their own care alongside their physicians (e.g. My Smart Age with HIV www.mysmartage.org/; the Happi App www.happiapp.eu).

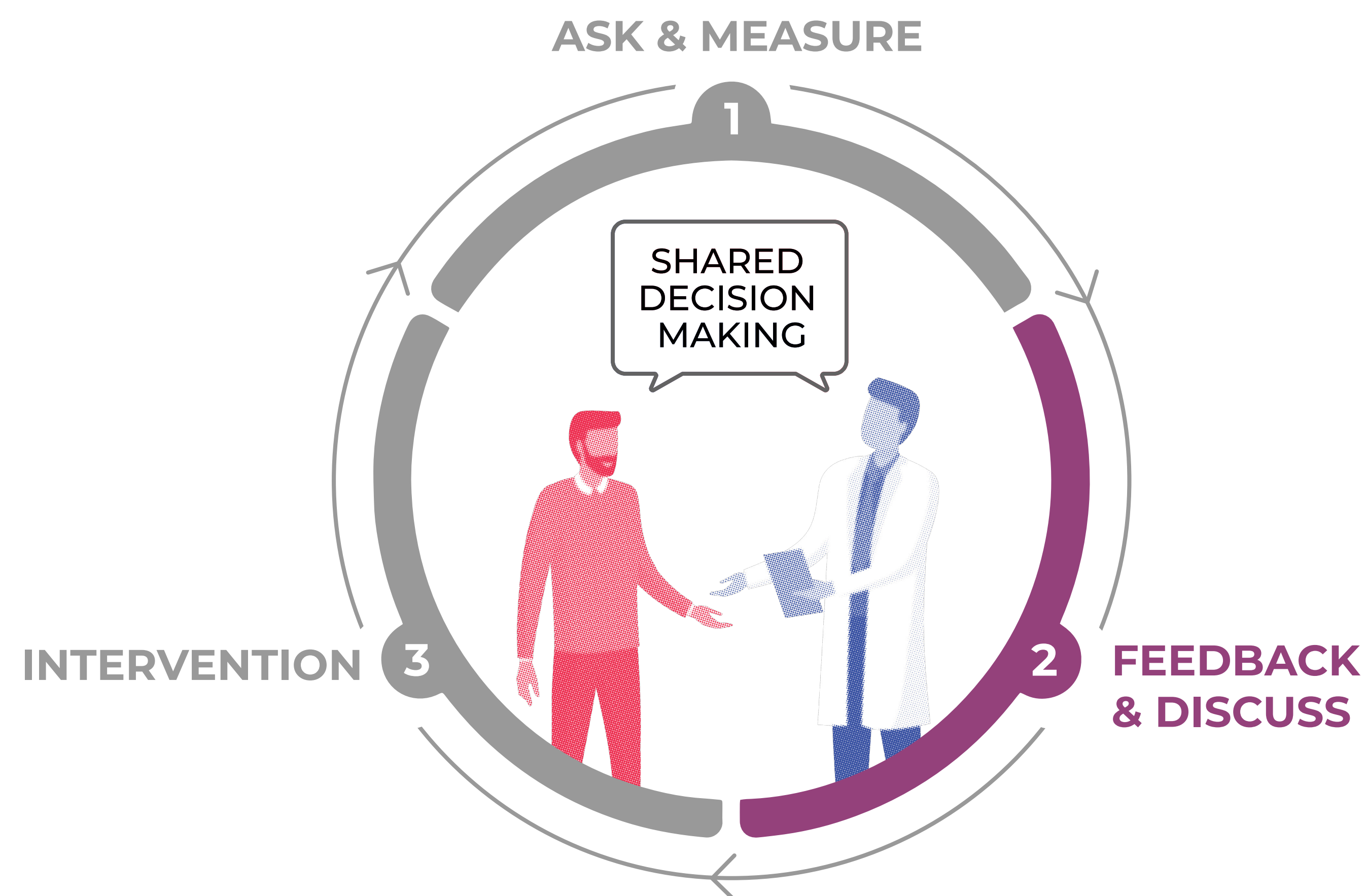


2 Feedback and discuss: sharing feedback and discussion of management options

Once measured, give the information back to the PLHIV, continually supporting the individual to share their information and understand its relevance to the choice of appropriate intervention

The Steering Committee observed that until a PLHIV knows why the information they have shared with the HCP is relevant and how it impacts decision-making, they may not see the use in sharing it. They may be uneasy about divulging information about their situation and may not understand the importance of making changes to their lifestyle or to their therapeutic regimen. Therefore, the process of asking the right questions, measuring the individual's health data and then, importantly, feeding back to the patient should be continuous throughout long-term care.

This Steering Committee reported that, as PLHIV become aware of their own health data and see the impact it has, they are more likely to make meaningful changes to their lives. This is an important part of the cyclical nature of the framework: if the person is shown how shared information makes a difference to the choice of treatment, it validates the time they took to share it. Thus, this second step of the 'health goals for me' framework is achieved by shared collaboration and is designed to empower the patient.



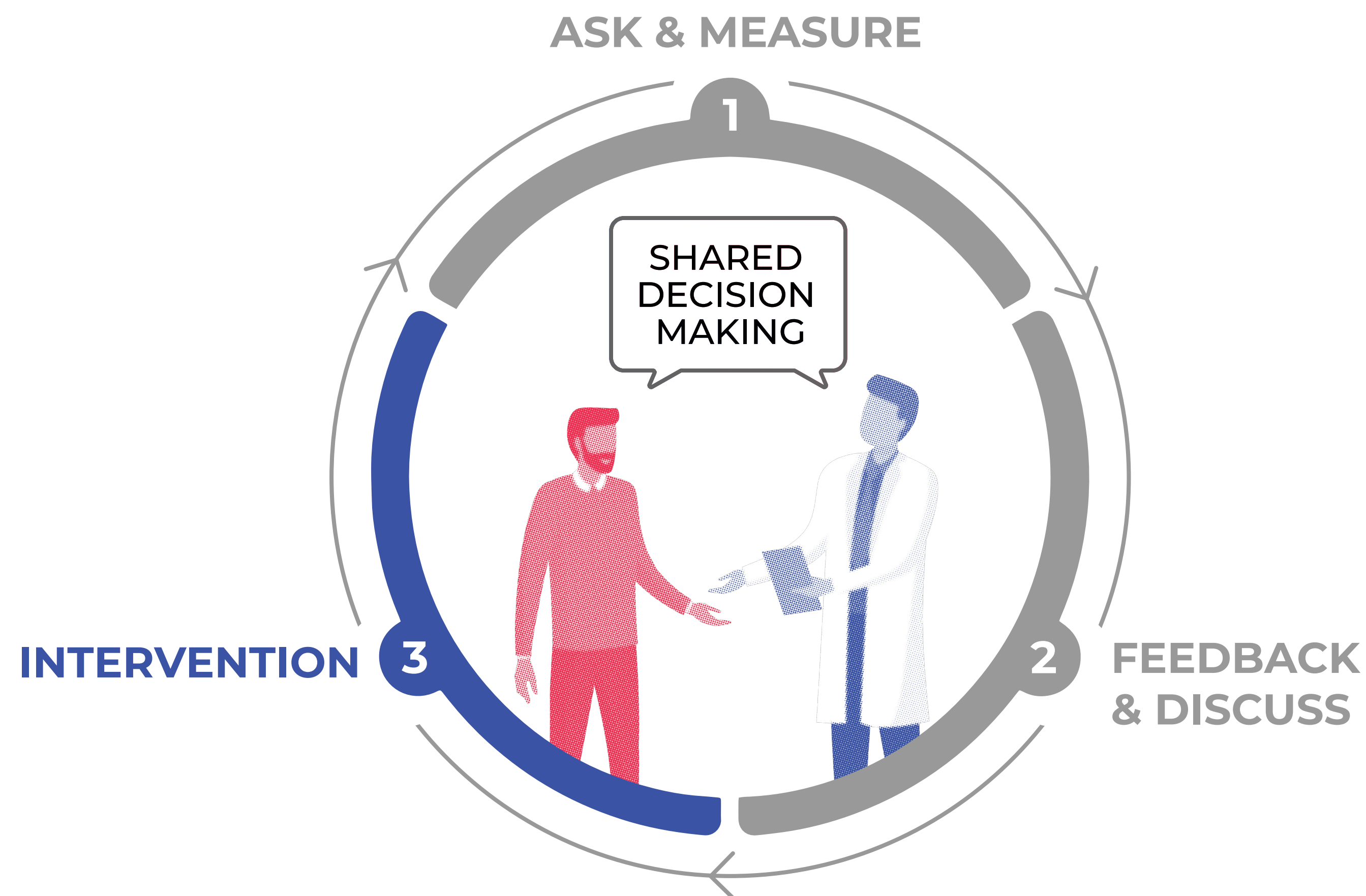
A vision towards achieving long-term healthy living in HIV

3

Intervention:

intervening to achieve long-term healthy living with HIV

Finally, measurements and feedback are provided, and common goals and a hierarchy of interventions are agreed between the HCP and PLHIV.



Once a full picture of the individual's health status is clear, the crux of the 'health goals for me' decision-making framework is to ensure collaboration and agreement between the HCP and the PLHIV on individual objectives for care, and ultimately, the choice of interventions to meet these objectives.

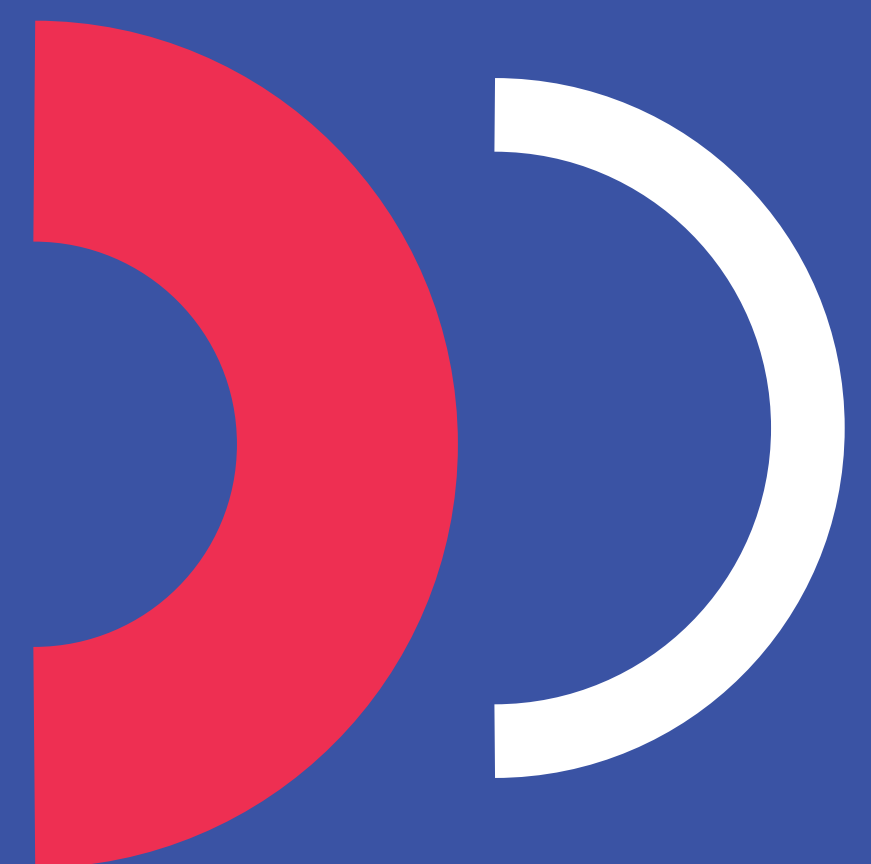
The end goal is not the asking, measuring and feeding back, but the reasons behind those questions, measurements and feedback. Healthcare professionals do not encourage people to count their steps for the sake of counting them, but because they have cardiovascular disease, or because they smoke. Discussing what has been measured and the reasons why, will allow the patient to be involved in the choice of intervention – whether that be to increase step count, or stop smoking, or take a medication to lower blood pressure.

While a collaborative approach is encouraged, the HCP should lead the discussion about what has been measured and the reasons why. While the patient can still have input (e.g. what lifestyle changes they can manage), the HCP knows which interventions can help – whether it is treatment change, lifestyle adaptation, counselling, referral to another specialist, or another intervention. Some individuals will naturally feel more empowered and confident in this process; however, it is the role of the HCP to identify the extent to which each person is willing and able to be involved in decision-making, and how to support each person to live healthily with HIV.

Conclusion and calls to action

This Steering Committee has a vision for the future of HIV care focused on achieving the fourth 90. They recognise the diversity of PLHIV and, thus, the need for a shift from focusing on HIV 'disease' to focusing on overall 'health'. Importantly, the aim of the Moving Fourth Steering Committee, this White Paper, and the 'health goals for me' framework is to empower HCPs and

PLHIV to collaborate and mutually agree on individual objectives for care, with the priorities of both parties considered in assessment and the therapeutic decision-making process. Ultimately, the Moving Fourth Steering Committee believes that this should become an intrinsic part of HIV care, to improve the long-term health and well-being of PLHIV.



Conclusion and calls to action

Making the vision a reality

Further work is needed to implement this framework in the real-world setting and to make this vision of long-term healthy living with HIV a reality. This includes defining good health-related QoL for PLHIV, ideally in both an objective and subjective manner in order to know what to measure; identifying which areas to assess beyond viral suppression; and designing patient-reported outcome questionnaires or other tools to address each of these areas.

Any such tools should be validated in PLHIV and should incorporate flexibility, by considering an individual's age or other factors. The use of e-health to facilitate

long-term healthy living with HIV may be advantageous and new technologies may be utilised for capturing patient-reported outcomes, which could be of particular use in resource-limited settings, in both developed and developing countries.²⁵ Empowering the patient in this way may help relieve the time and resource constraints on healthcare systems. Ideally, any further work should be adopted globally to help guarantee access to treatment and long-term disease management for every HIV-positive person.





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