

Let's Talk

SIDE

EFFECTS

Research Brief



Dr. Marilou Gagnon, RN, PhD
Dr. Dave Holmes, RN, PhD

BACKGROUND

Despite the introduction of new (and supposedly less toxic) antiretroviral drugs and the simplification of treatment options (i.e., all-in-one combination tablets), side effects continue to affect people living with HIV (PLWH).^{1,2,3,4} Short term and long term side effects are well documented in PLWH. Short term side effects typically include gastrointestinal toxicities (e.g., diarrhea, nausea, vomiting, and bloating), central nervous system toxicities (e.g., vivid dreams, off-balance or unsteady walking, light-headedness, drowsiness, feeling “hungover”, feeling like falling over, spinning or room spinning, difficulty concentrating), fatigue, anemia, hypersensitivity reactions, and drug-induced organ toxicities.² Short term

side effects can dissipate on their own after weeks and months of treatment, but they can also persist over time and have long-lasting effects on PLWH. Long term side effects include cardiovascular, hepatic, renal, metabolic, neurologic, and musculoskeletal events such as myocardial infarction, hepatotoxicity, renal dysfunction, dyslipidemia, insulin resistance, diabetes, lipodystrophy, peripheral neuropathy, cognitive deficits, and bone loss.² Side effects are central to the experience of living with HIV and living with the HIV treatment but they have not been studied alone. In this brief, we present the findings of a qualitative study on side effects and key recommendations.

1 Esté, J.A., & Cihlar, T. (2010). Current status and challenges of antiretroviral research and therapy. *Antiviral Research*, 85 (1), 25-33.

2 Hawkins, T. (2010). Understanding and managing the adverse effects of antiretroviral therapy. *Antiviral Research*, 85 (1), 201-209.

3 Margolis, A.M., Heverling, H., Pham, P.A., & Stolbach, A. (2014). A Review of the toxicity of HIV Medications. *Journal of Medical Toxicology*, 10, 26-39.

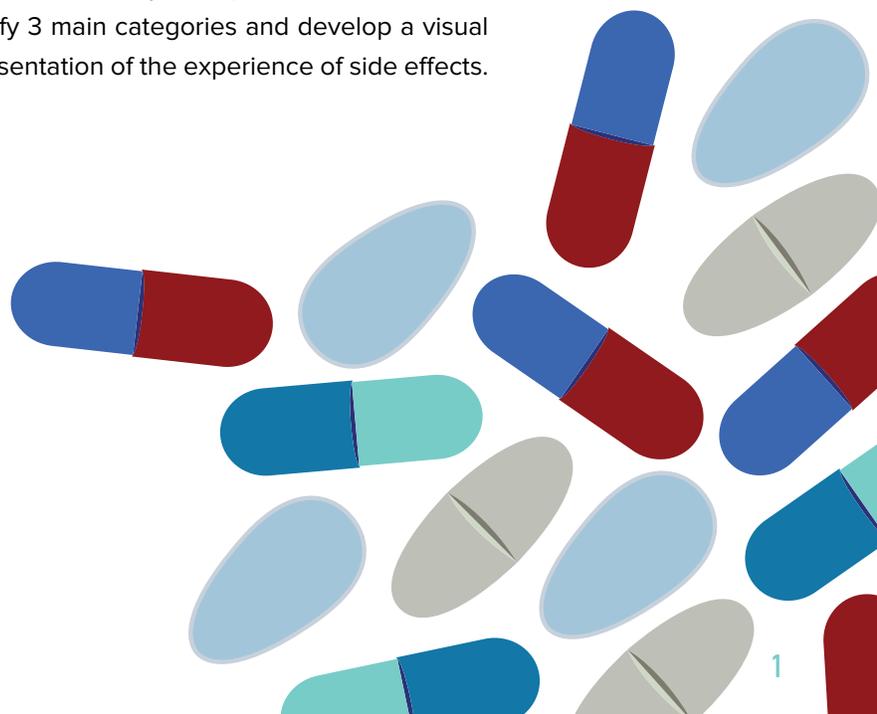
4 Reust, C.E. (2011). Common Adverse Effects of Antiretroviral Therapy for HIV Disease. *American Family Physician*, 83 (1), 1443-1451.

STUDY

This two-year study was designed to gain a better understanding of the experience of side effects and develop an alternative approach to think about this. We conducted a total of 50 interviews in the National Capital region. This region includes the cities of Ottawa (Ontario), Gatineau (Quebec), and their surrounding communities. In order to be included in the study, participants had to self-identify as persons living with HIV and be able to communicate in French or English. All participants had to be 18 years old or older. Participants could take part in the study if they were taking antiretroviral drugs or confirmed that they had been taking antiretroviral drugs less than 6 months ago.

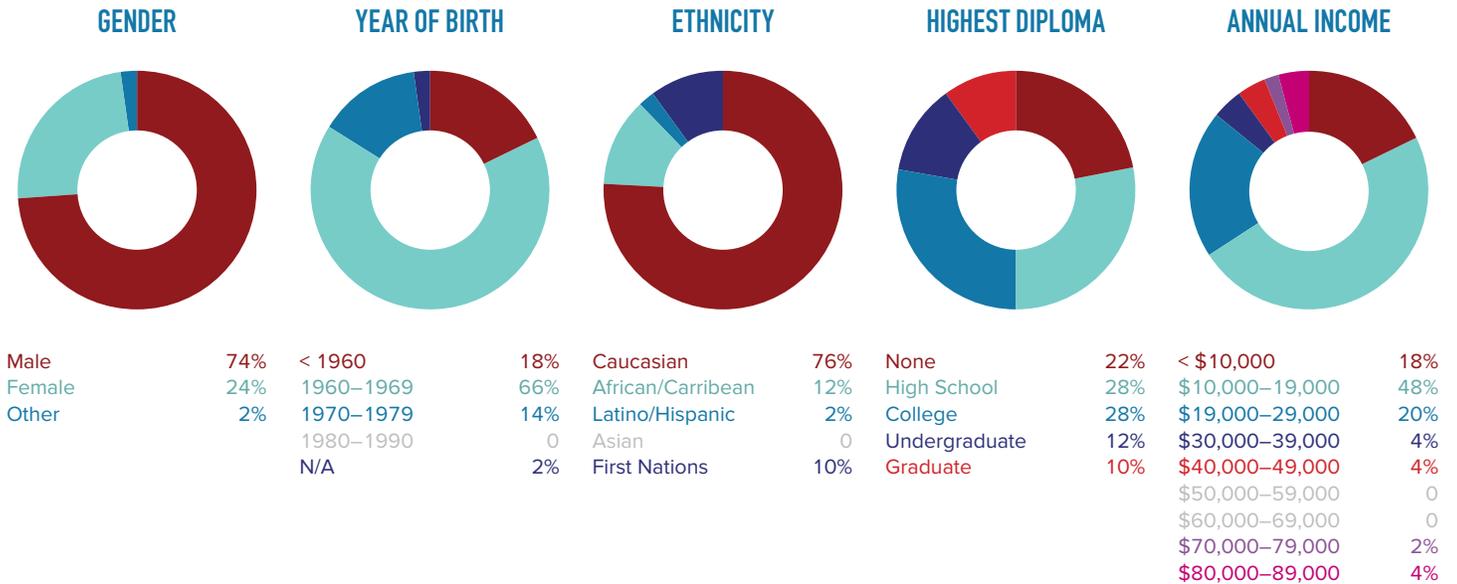
At the beginning of the interview, participants were asked to describe their experience with antiretroviral drugs over time and how they impacted their life in general and on a day-to-day basis. Then, they were asked to describe their experience with side effects with a particular

focus on the way side effects manifested themselves, how they made them feel, what they meant, and how they were managed. Finally, they were asked to describe what it means to live with side effects. Each interview was audio-recorded using a digital voice recorder, transcribed, and analyzed using the principles of grounded theory. This process allowed us to identify 3 main categories and develop a visual representation of the experience of side effects.



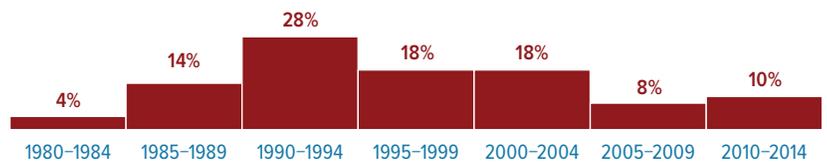
STUDY PARTICIPANTS

On average, participants were born between 1960 and 1969 (66%). Most of the participants were male (74%). Female participants accounted for 24% of the sample. The vast majority of participants had an annual income below \$30,000 CAN (86%). 14 participants had a high school diploma, 14 had a college degree, and 11 had a university degree (including undergraduate and graduate levels).



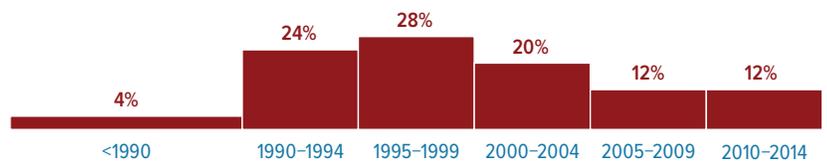
The year of diagnosis was distributed as such within the group. The year of diagnosis is important to consider in this study because it gives us an indication of the antiretroviral drugs that participants were first exposed to.

YEAR OF DIAGNOSIS



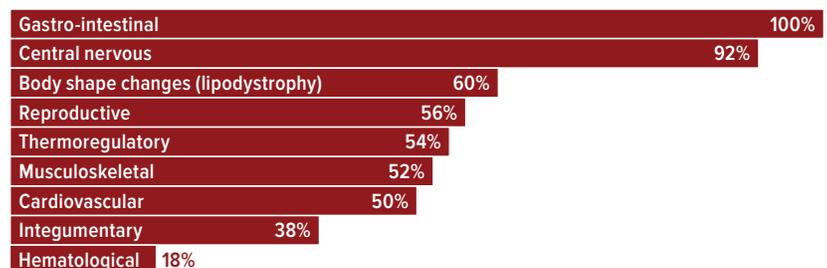
Some participants started taking antiretroviral drugs before 1996 combination therapy had not been introduced and when antiretroviral drugs were still considered experimental. Others participants first started taking antiretroviral drugs after the introduction of combination treatment but they were exposed to different first-line regimens depending on the time of initiation.

YEAR OF FIRST TREATMENT



Gathering information on side effects and summarizing it in tables was challenging because PLWH experience a lot of side effects and are exposed to numerous treatment combinations over time. The table on the right summarizes the side effects reported by participants per body system.

SIDE EFFECTS (BY BODY SYSTEM)



KEY FINDINGS

THE SIDE EFFECTS

CONTEXT

TYPES

NATURE

THE EXPERIENCE

BECOMING
WITH

LIVING
WITH

DEALING
WITH

THE CONNECTIONS

PEOPLE

THINGS

SYSTEMS

1 THE SIDE EFFECTS

CONTEXT

TYPES

NATURE

The context in which participants first experienced and continued to experience side effects as well as the types and nature of side effects were identified as key sub-categories during the analysis. Participants started taking antiretroviral drugs at various times in the history of the HIV epidemic. That historical context gave particular meaning to their side effects and the drugs themselves. As such, it was a key determinant of their experience.

Participants developed side effects in various treatment contexts: during pregnancy, during a clinical trial, after the initiation of their first treatment regimen, after switching to a new regimen and/or a newly marketed antiretroviral drug, after switching one antiretroviral drug in their regimen, after switching back to a previous antiretroviral drug, and so forth. Paying close attention to that context proved essential to capture the diversity of their experiences.

We identified different types of side effects: immediate–progressive, transient–permanent, hidden–visible, and minor–severe. These helped illustrate the complexity of side effects. We also identified three characteristics of side effects: 1) they are unpredictable: you never know how you are going to react and when they will manifest themselves, 2) they are unstable: things change from one day to the next, and 3) they are highly individual: every person is unique.

2 THE EXPERIENCE

BECOMING WITH

LIVING WITH

DEALING WITH

At the core of the experience of side effects, we found three interrelated processes: becoming with, living with, and dealing with. The experience of side effects was described as a process of becoming both healthy and sick at the same. They were healthy “on paper” but they felt sicker than ever before because of the side effects. It was also described a process of becoming another version of yourself and redefining their “normal”: what is a normal life, a normal day, a normal body.

All of the participants talked about the experience of living with side effects and what that entailed. Living with side effects came with many uncertainties: not knowing how they would feel from one day to the next, not knowing what is a side effect and what is not, and not knowing what the future holds were repeatedly mentioned by participants. Living with side effects also came with many limitations including physical, mental, and functional limitations.

Participants described the various ways in which they tried to deal with side effects and the specific strategies they used. As part of the process of dealing with side effects, they had to deal with their treatment by deciding to continue, switch, or stop. They also had to deal their HIV physician. This was challenging for the majority of participants who struggled to be heard in the face of treatment optimism and have their side effects recognized and managed.

- Taking additional prescribed medications
- Using over-the-counter medications
- Smoking marijuana
- Taking supplements
- Changing diet
- Changing fluid intake
- Changing lifestyle
- Monitoring (e.g., weight, blood pressure, glucose, blood tests)
- Changing the medication schedule (e.g., time of the day)
- Doing tests
- Doing research on the internet
- Talking to others

3 THE CONNECTIONS

PEOPLE

THINGS

SYSTEMS

Three types of connections were identified: connections with people, things and systems. We found that side effects created new connections with three groups of people: medical specialists, specialized health care providers, and peers. Participants found connections with peers who shared the experience of taking the same antiretroviral drugs, having the same side effects, dealing with these side effects, and facing similar challenges most valuable.

In addition to creating new connections with people, side effects created new ways of connecting with three categories of “things”: drugs, devices, and objects. Side effects increased the presence of drugs and medical devices (e.g., glucometers) in the lives of participants. They also profoundly changed the way participants related to familiar objects in their environment (the toilet for example) as well as their relationship to food and fluids.

Three systems shaped the experience of side effects: the knowledge systems, the health care system, and the state welfare system. We identified two competing knowledge systems: the dominant system of scientific and medical knowledge on side effects and the alternative system created by PLWH (as experts). We also found that participants developed strong ties to the health care and the state welfare systems (e.g., social assistance, housing, food) as a direct result of their side effects.

RECOMMENDATIONS

Based on the study findings, we propose the following recommendations and priorities:

RETHINK SIDE EFFECTS ALTOGETHER

The current framework does not work. It does not work for PLWH and it does not work for health care providers. It oversimplifies an experience that is highly individual and complex. It is imperative to develop a new framework that reflects the types of side effects described in this study and the nature of the experience reported by PLWH. This is the first step in improving our response to side effects.

PAY CLOSER ATTENTION TO CONTEXT

The experience of side effects is context-dependent. As such, it is important to place it in its historical context and take into account the contexts of diagnosis, treatment initiation, and treatment experience. It is also important to look at the context in which PLWH are experiencing and dealing with their side effects. This can provide important information on challenges they may face and how to address them.

ASK MORE QUESTIONS

We need to ask more questions about side effects. While this recommendation applies to service providers and researchers, it is particularly directed at health care providers. Health care providers have an important role to play in the assessment, recognition, and management of side effects. To assist health care providers, we developed a list of 10 questions that should be asked in clinical settings (page 7).

LISTEN TO PEOPLE LIVING WITH HIV

Listening and responding to what PLWH have to say about their medications, their side effects, and their bodies is basic—yet extremely important. Side effects are subjective and unique. Their impact is very real and personal. When they are minimized, dismissed, or normalized, it causes a great deal of harm to PLWH—despite good intentions.

RECOGNIZE THE IMPACT OF SIDE EFFECTS

The far-reaching impact of side effects needs more attention. The physical impact of side effects can range from a slight discomfort to a chronic disability. The mental impact includes the actual effects of antiretroviral drugs on the brain, the psychological effects of taking the drugs, and the burden of HIV stigma. Side effects can also contribute to social isolation and precarious living.

FIND ALTERNATIVE SOLUTIONS

Side effects are predominantly managed with additional medications. This is part of the problem according to PLWH. Finding alternative solutions, such as the prescription and use of medical marijuana, is a key recommendation to improve the way side effects are managed in clinical practice. Rethinking side effects (as mentioned above) may actually help to rethink solutions.

DEVELOP NEW RESOURCES

Very few resources exist for PLWH, service providers and health care providers. Recommendations to address this gap include developing resources that: 1) Take into account the lived experience expertise of PLWH, 2) Support changes in clinical practice—from the assessment to the management of side effects, and 3) Operationalize a new way of thinking about side effects.

CHANGE THE MODEL OF CARE

Side effects are primarily conceived as a medical problem—one that should be primarily managed by HIV physicians with limited involvement from other health care providers. This model of care is inadequate according to PLWH. Efforts should be made to change the model of care by identifying the needs (e.g. educational, practical, and informational) of PLWH and increase the involvement of nurses and pharmacists.

INCLUDE SIDE EFFECTS IN THE CONVERSATION

Side effects need to be part of the conversation on HIV treatment, instead of being erased from it. This conversation has become increasingly focused on the idea that HIV treatment is now simpler, more manageable, better tolerated, less toxic, and more effective. Unless we change this conversation, it is unlikely that the issues highlighted above will be addressed anytime soon.

CREATE A NEW SYSTEM FOR COLLECTING DATA AND REPORTING

Comprehensive data on side effects and appropriate mechanisms for reporting side effects are lacking. We need an independent online system where PLWH can report their side effects and conduct their own research on antiretroviral drugs. Building on the model proposed by Rxisk (<http://rxisk.org/>), this system could also increase the capacity to report side effects directly to Health Canada.

POLICY PRIORITIES

- Provide universal pharmacare
- Ensure full coverage of nutritional supplements
- Raise welfare and disability rates
- Support PLWH returning to work
- Increase access to affordable housing
- Increase access to nutritious food
- Legalize marijuana

10 QUESTIONS HEALTH CARE PROVIDERS SHOULD ASK ABOUT SIDE EFFECTS

These questions should be used to start a conversation on side effects. They are not meant to be prescriptive. The goal is to provide a few questions that can help identify the needs of patients and improve the care provided in the context of side effects.

In addition to asking patients to identify their side effects on a checklist or body map and conducting a full treatment and side effects history, you should consider asking the following questions:

- 1 DO YOU STILL HAVE SIDE EFFECTS FROM PAST TREATMENT REGIMENS? WHICH ONES?**
- 2 ARE THERE SIDE EFFECTS THAT YOU ARE UNSURE ABOUT? WHICH ONES? WHY?**
- 3 WHICH SIDE EFFECTS ARE MINOR AND WHICH ONES ARE SEVERE TO YOU?**
- 4 IS THERE A TIME WHEN SIDE EFFECTS ARE WORST (DAY, NIGHT, WEEK, OR MONTH)?**
- 5 IS THERE ANYTHING YOU CANNOT DO ANYMORE BECAUSE OF SIDE EFFECTS?**
- 6 HOW DO YOU DEAL WITH SIDE EFFECTS? WHAT DO YOU DO? WHAT HAS BEEN HELPFUL TO YOU?**
- 7 WHICH SIDE EFFECTS ARE MANAGEABLE AND PREDICTABLE? WHICH ONES ARE NOT?**
- 8 WHERE DO YOU GET YOUR INFORMATION ON SIDE EFFECTS?**
- 9 DO YOU FEEL HEALTHY? SICK? BOTH?**
- 10 WHAT DOES IT MEAN TO LIVE WITH SIDE EFFECTS?**

SUGGESTED CITATION

Gagnon, M. & Holmes, D. (2016). Let's Talk Side Effects: Research Brief. Ottawa, CANADA.

RESEARCHERS

Dr. Marilou Gagnon, RN, PhD, Associate Professor (marilou.gagnon@uottawa.ca) and Dave Holmes, RN, PhD, Full Professor (dholmes@uottawa.ca) at the School of Nursing, Faculty of Health Sciences, University of Ottawa (ON), Canada.

FUNDING

This study was funded by the Canadian Institutes of Health Research (CIHR).

ETHICS

This project was approved by the Office of Research Ethics and Integrity at the University of Ottawa (H09-13-14B).

RESEARCH PAPER

The full description of the study and the study findings is available online for free.

The research paper has been published in Aporia: The Nursing Journal, volume 8, issue 1:

<http://www.oa.uottawa.ca/journals/aporia/>

TRANSLATION

Elie Darling

DESIGN

pulp&pixel – www.pulpandpixel.ca

