CATIE
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Understanding the experience of side effects: 50 people living with HIV share their stories

Marilou Gagnon, RN, PhD, Associate Professor
School of Nursing | Faculty of Health Sciences | University of Ottawa

☎ Please make sure you access the audio portion:
Toll-free access number: 1-866-500-7712
Access code: 3970509

The webinar will commence shortly.

All participants will be muted until the question period.

Marilou Gagnon, RN, PhD

Dr. Marilou Gagnon is Associate Professor at the School of Nursing, Faculty of Health Sciences, University of Ottawa and Director of the Unit for Critical Research in Health.

UNDERSTANDING THE EXPERIENCE OF SIDE EFFECTS: 50 PEOPLE LIVING WITH HIV SHARE THEIR STORIES

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CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

CANAC
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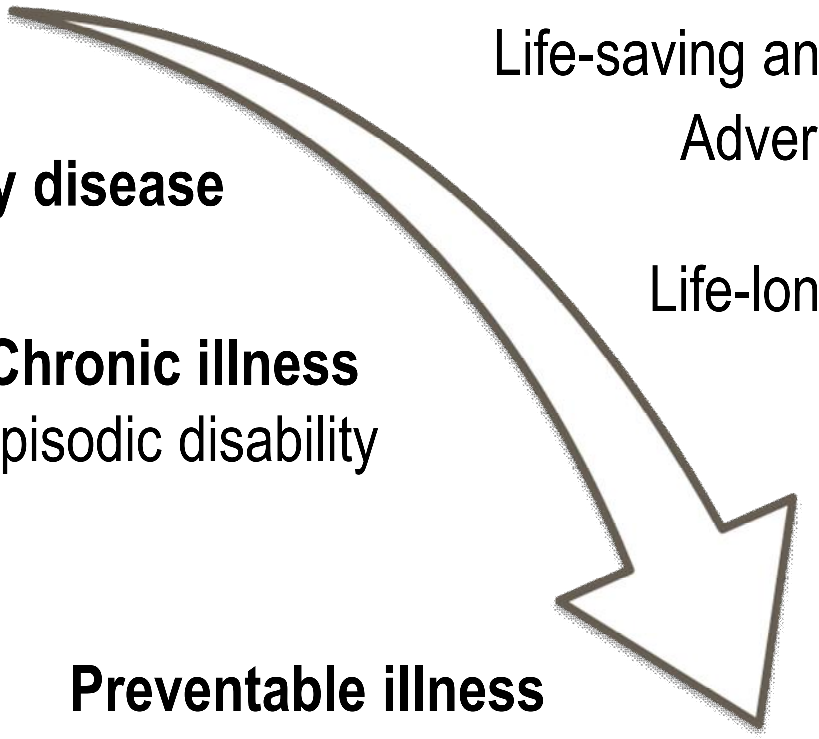
OUTLINE

- Context
- Study
- Results
- Recommendations
- Resources
- Next steps

HISTORICAL CONTEXT



Deadly disease

Life-saving and toxic treatment

Adverse or side effects (deadly)

Chronic illness
Episodic disability

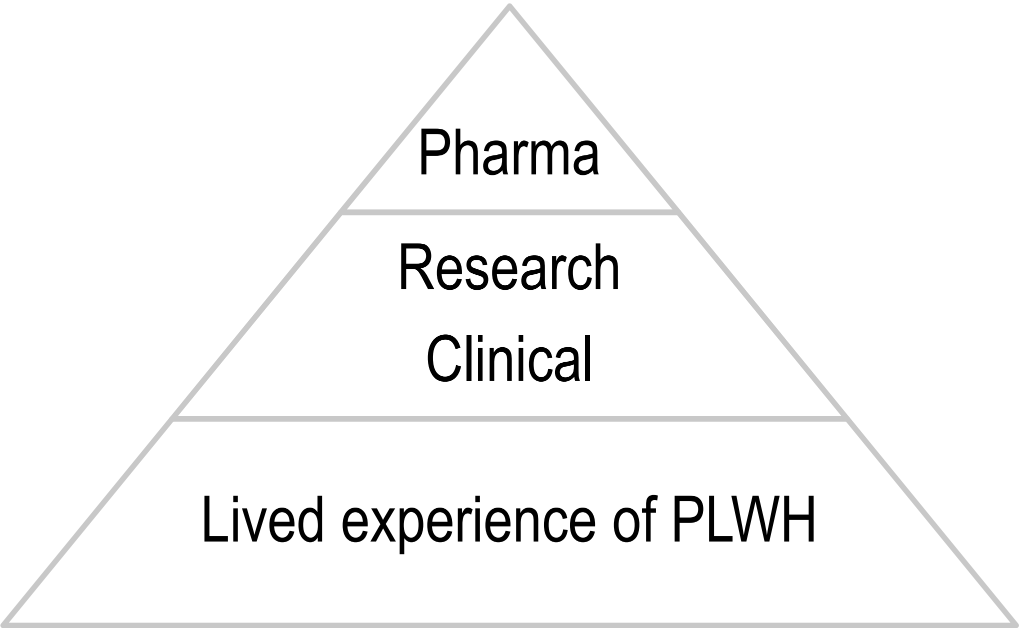
Life-long and «manegeable » treatment
Symptoms
(chronicity and aging)
Limitations (disability)

Preventable illness

Treatment as prevention
« *Same-day treatment* »

STATE OF KNOWLEDGE

- Sources
  - Pharmaceutical companies
  - Researchers and clinicians
  - People who take medications



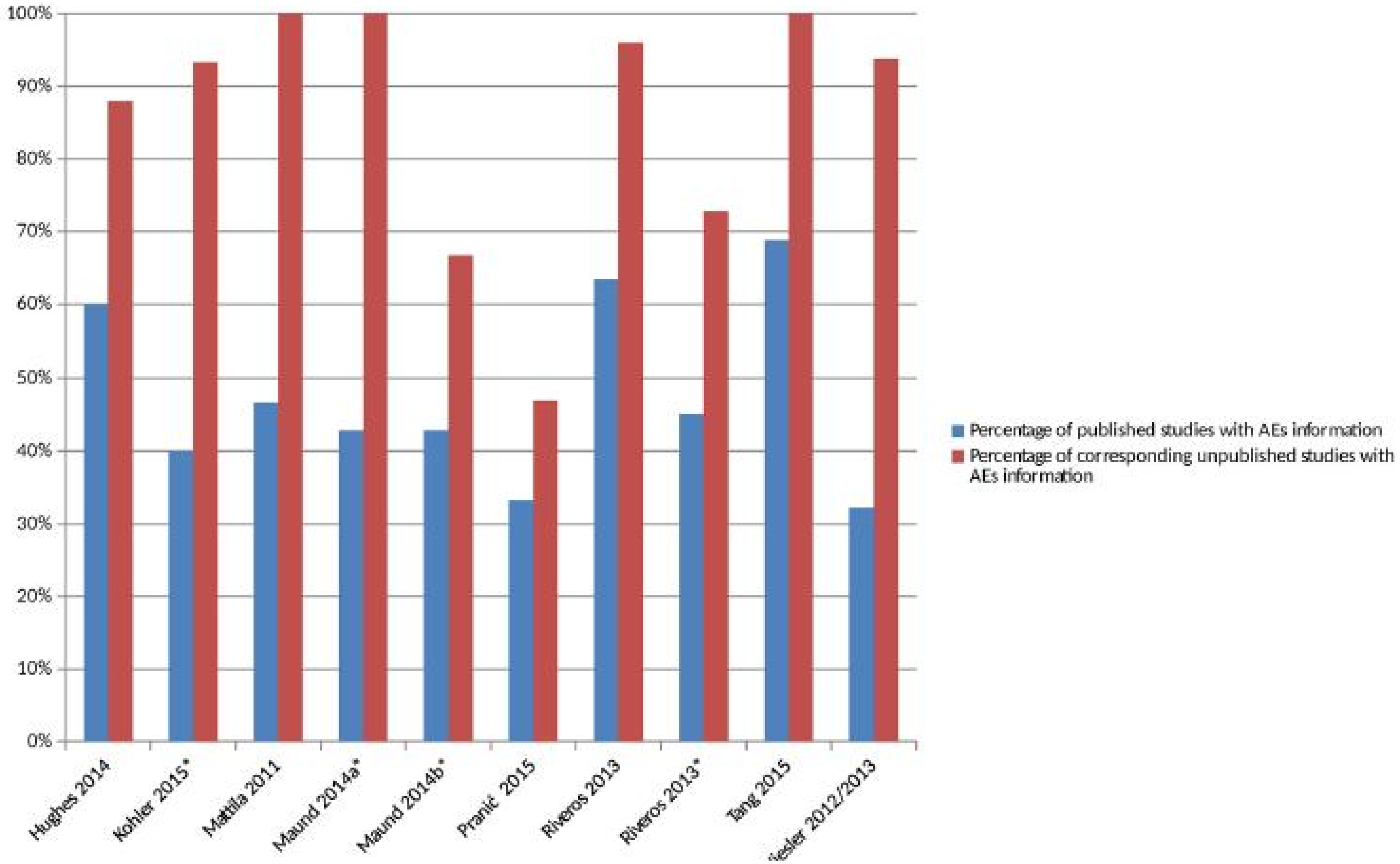
Pharma

Research
Clinical

Lived experience of PLWH

STATE OF KNOWLEDGE

- Sources : unpublished versus published side effects (Golder et al. 2016)



STATE OF KNOWLEDGE

- Sources : clinical trials vs « real life » (HIV Drug Therapy Congress, Glasgow 2016)

NEWS

Further Reports of CNS-Related Side Effects With Dolutegravir

By Simon Collins
October 26, 2016
From HIV i-Base

Several studies at Glasgow 2016 provided additional information about real world experience with the integrase inhibitor dolutegravir.

Although registrational studies showed that dolutegravir has higher efficacy and fewer side effects compared to many other drugs, post marketing experience has included higher reports of CNS-related side effects in a minority of patients.

Neuro effects more frequent
Women (2.64)
Older adults (> 60 years) (2.86)
Disappear after treatment cessation
Dizziness
Nervousness
Depression
Headaches
Insomnia
Difficulties concentrating
Pain

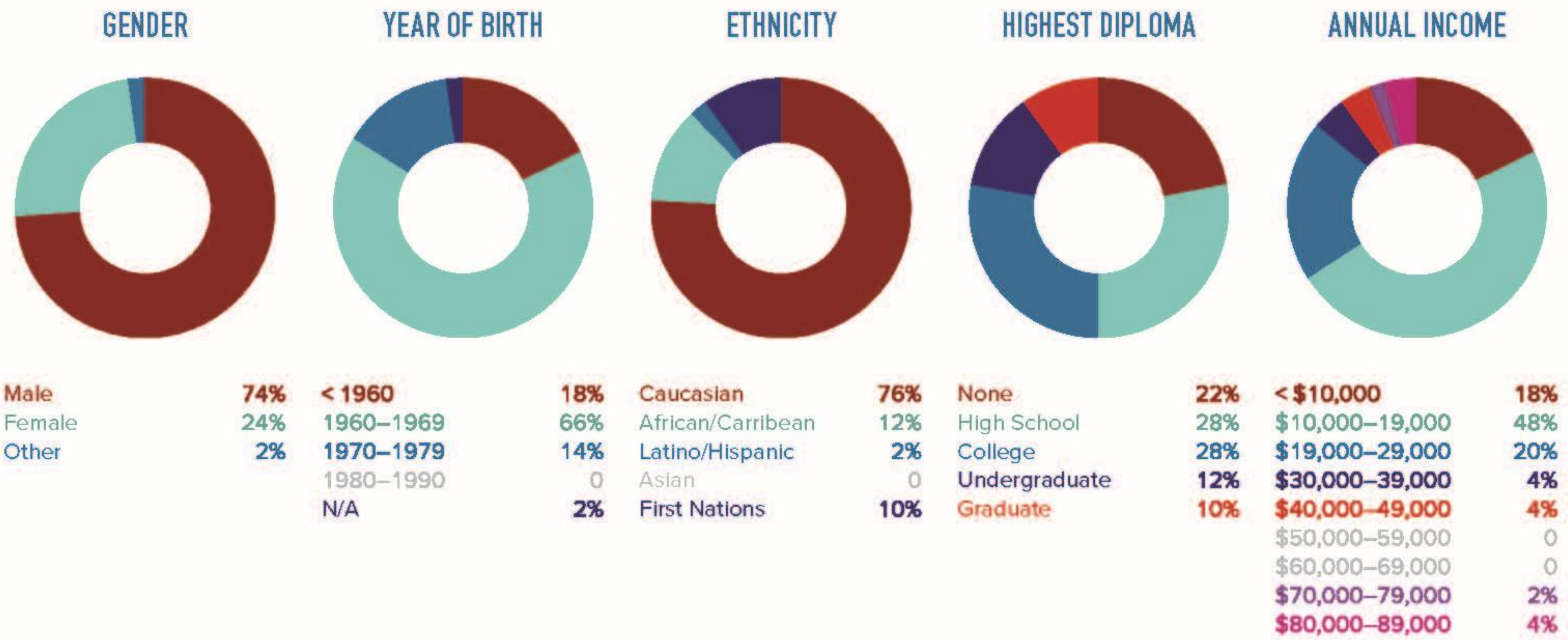
STATE OF KNOWLEDGE

- No data on prevalence (ATLIS, 2010)
    - 40% did not like how medications made them feel
    - 50% said medications had negative impact on quality of life
    - 25% had never talked to their provider about side effects
- Homogeneous population
    - Little data on women and older adults
- Controlled environment
    - Little data in « real life » context
- Classification of side effects by:
    - Medication / Class (family) / Types / Body systems
- What about the experience of PLWH?

STUDY

- Qualitative study (grounded theory)
- Funded by the Canadian Institutes of Health Research
- National capital region (Gatineau and Ottawa)
- Recruitment (posters and e-mails via community-based organizations)
- Sociodemographic questionnaire and information on side effects
- Individual interviews
  - Experience with medications and side effects
  - What does it mean to live with side effects?
- 50 participants

PARTICIPANTS



GENDER

Male	74%
Female	24%
Other	2%

YEAR OF BIRTH

< 1960	18%
1960–1969	66%
1970–1979	14%
1980–1990	0
N/A	2%

ETHNICITY

Caucasian	76%
African/Carribean	12%
Latino/Hispanic	2%
Asian	0
First Nations	10%

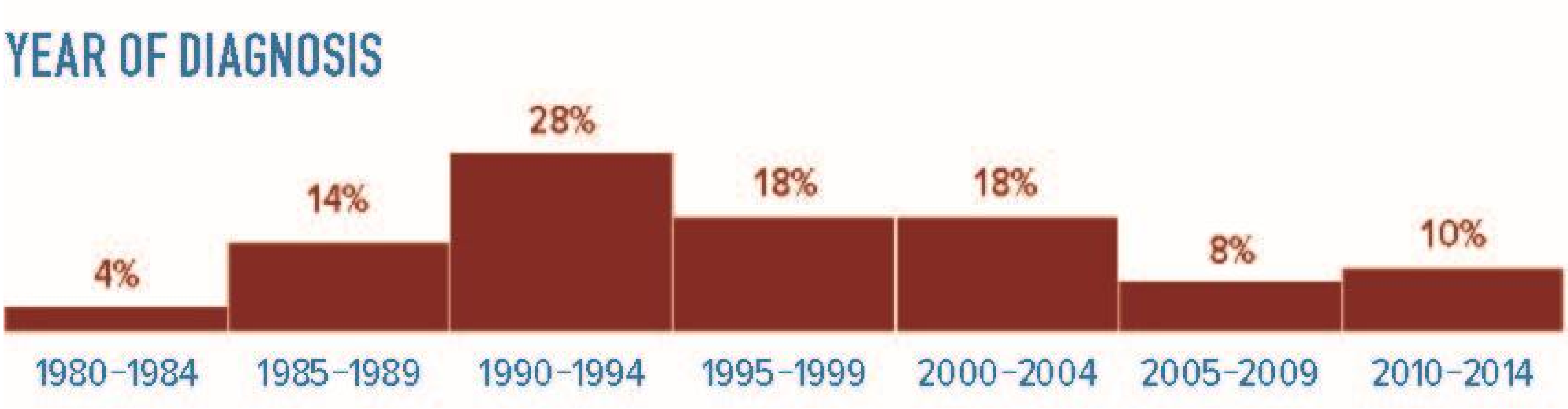
HIGHEST DIPLOMA

None	22%
High School	28%
College	28%
Undergraduate	12%
Graduate	10%

ANNUAL INCOME

< $10,000	18%
$10,000–19,000	48%
$19,000–29,000	20%
$30,000–39,000	4%
$40,000–49,000	4%
$50,000–59,000	0
$60,000–69,000	0
$70,000–79,000	2%
$80,000–89,000	4%

PARTICIPANTS



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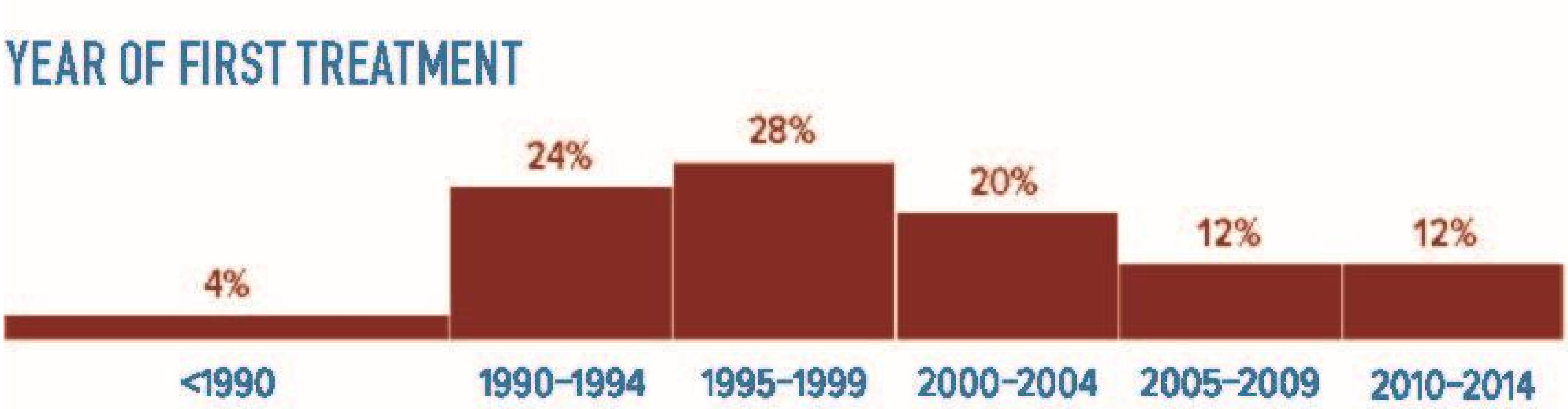
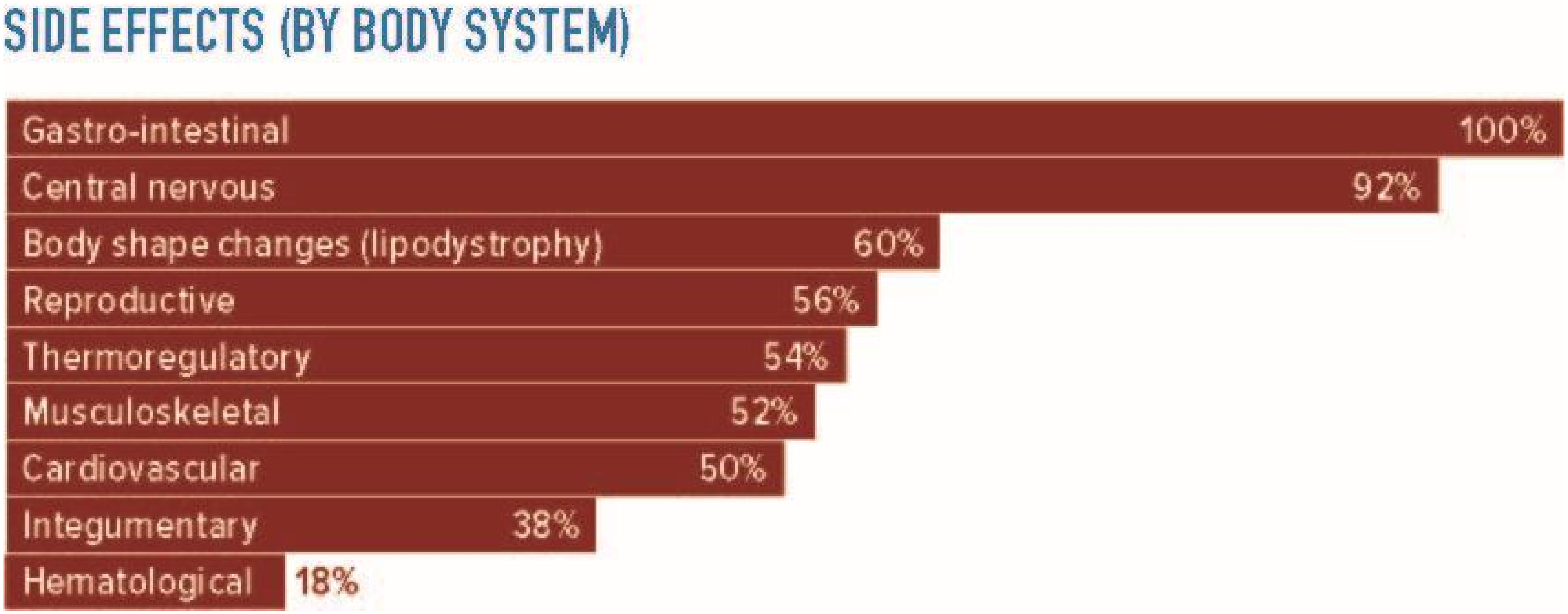
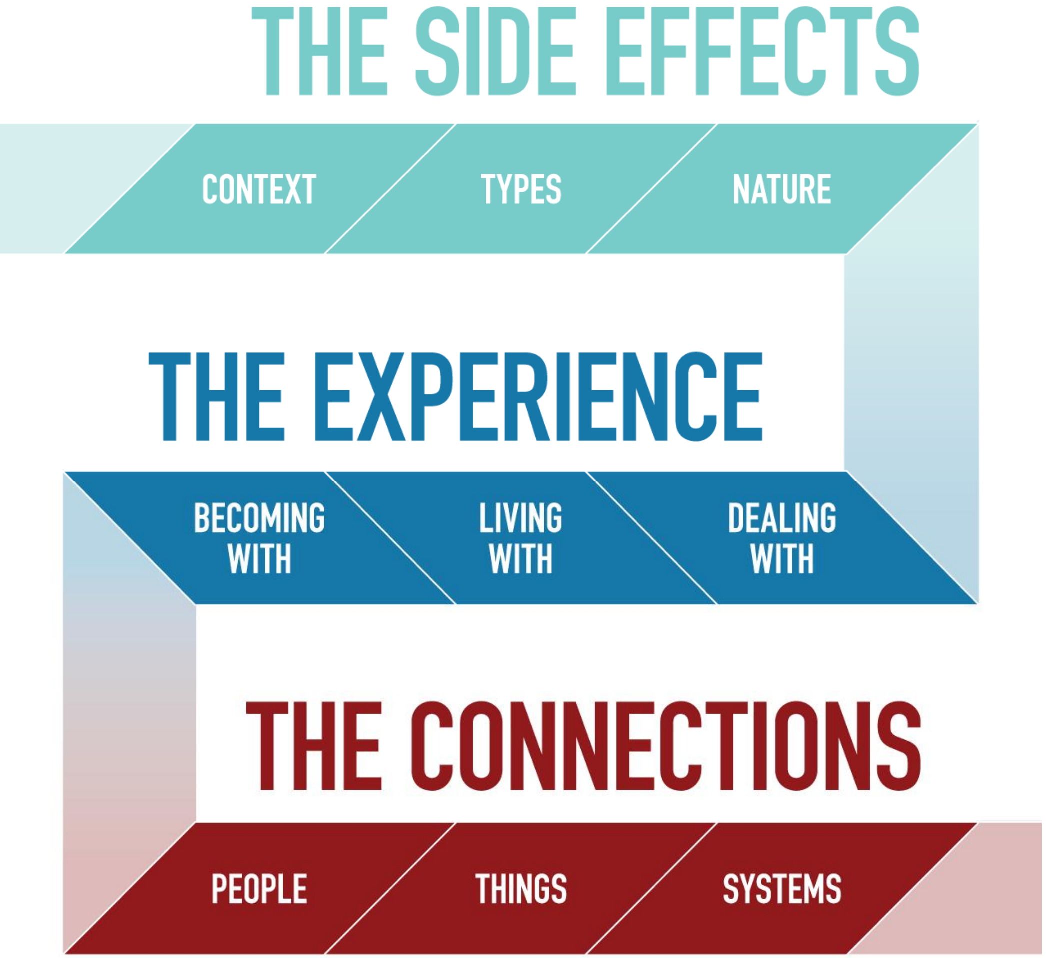


PARTICIPANTS



RESULTS



THE SIDE EFFECTS

CONTEXT | TYPES | NATURE

THE EXPERIENCE

BECOMING WITH | LIVING WITH | DEALING WITH

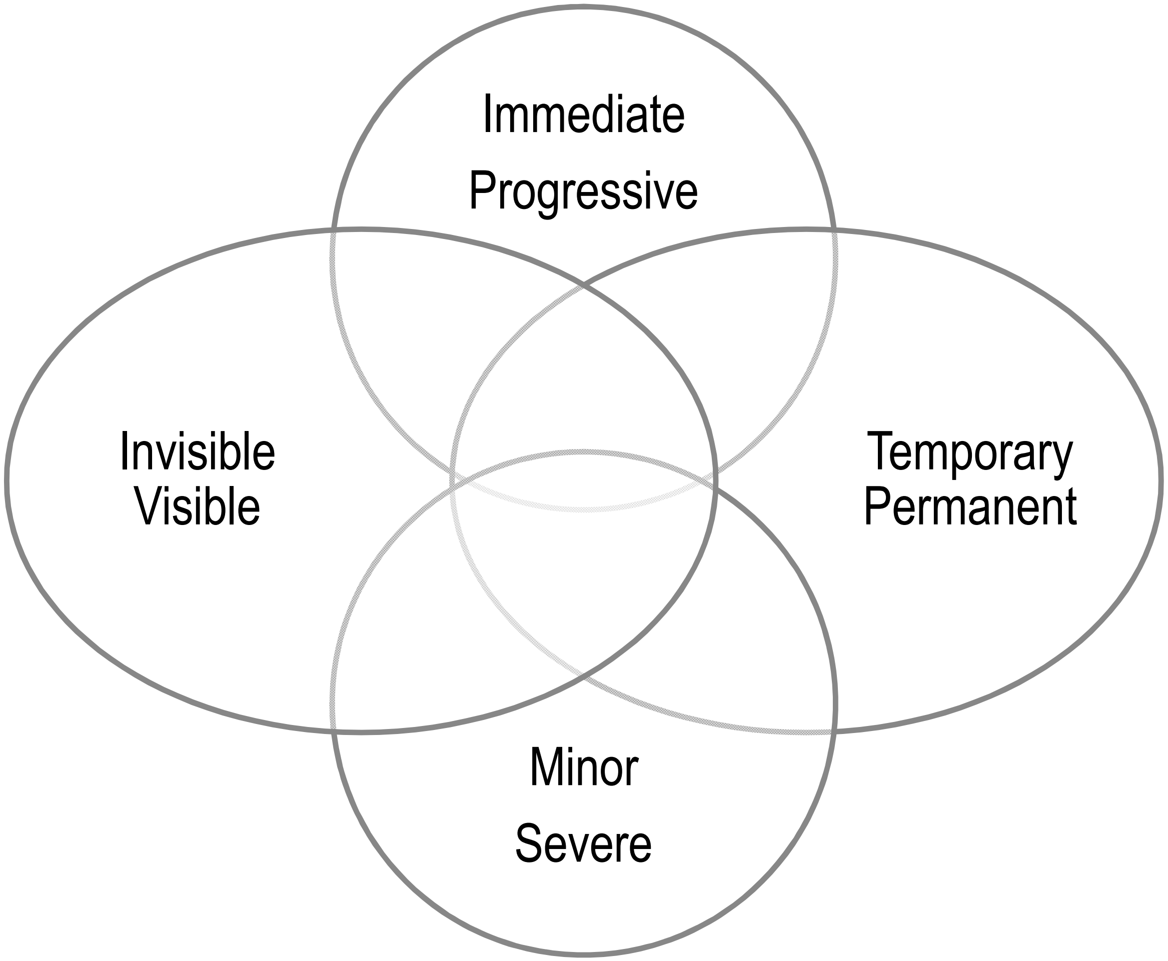
THE CONNECTIONS

PEOPLE | THINGS | SYSTEMS

THE SIDE EFFECTS | Context

- Epidemic
  - What was happening at the time?
  - Where were we at with the medications?
  - How did we talk about side effects? What about today?
- Treatment
  - In what context did they start the treatment (especially first treatment)?
    - During a pregnancy
    - During a clinical trial
    - After changing the treatment
    - After starting a new treatment (new medications available)
    - At the time of diagnosis

THE SIDE EFFECTS | Types



Immediate
Progressive

Invisible
Visible

Temporary
Permanent

Minor
Severe

THE SIDE EFFECTS | Types

- Type 1
  - Immediate
    - Variable (from nausea to hepatoxicity) and easy to recognize
  - Progressive
    - Subtle (loss of energy) and harder to recognize
- Type 2
  - Temporary / disappear eventually with time
    - « Body adjusting » to the medications
  - Permanent / persist in time
    - Same treatment (diarrhea)
    - Despite changes in treatment (lipodystrophy)

THE SIDE EFFECTS | Types

- Type 3
  - Invisible
    - Easier to live with, more control, less impact
    - Diabetes and MI easier than lipodystrophy
  - Visible
    - Harder to live with, less control, more impact
    - Lipodystrophy : body image, disclosure, stigma
    - Diarrhea : shame, judgment of others, isolation (family)
    - Pasty mouth: isolation (intimacy), self-esteem, rejection
- Impact on self, self-image, body, and interactions with others

THE SIDE EFFECTS | Types

- Type 4
  - Minor – Severe based on the impact on:
    - Activities of daily living
    - Social interactions
    - Self-esteem
    - Global health (physical, mental, sexual health)
  - Based on the ability to manage and lessen side effects

when "something that could easily be managed, turns into something where you want to throw yourself off the balcony"

THE SIDE EFFECTS | Nature

- Three characteristics
  - Unpredictable
    - You never know how you are going to react and you never know when side effects will appear (day, week, month)
  - Unstable
    - Things change from one day to the next
  - Individual
    - Every person is unique
      - Differences between men and women
      - Importance of knowing yourself
      - Importance of finding what works for you

THE EXPERIENCE | Becoming with

- Becoming sick (being reminded about HIV) and « healthy »
- Becoming a new version of yourself (a lesser version)
- Becoming your new « normal » : normal life, normal day, normal body

Living with the effect of medication … It basically means that I'm sick. It means, well, here's the result of this virus that must be controlled. We have to control it to stay healthy and at the same time, it causes side effects. So for me, that's what it means. For me it's like, "yes, you're really sick" and "yes, your capacities are diminished". Because of the medications, I have this, I have that. It never ends.

THE EXPERIENCE | Living with

- Learning to « live with »
  - Adapt, endure, accept, get used to, adjust, etc.
- Living based on the rhythm of the medications
- Living with uncertainties
  - How you will feel from one day to another
    - « Live day by day » (like a rollercoaster)
    - Impact on social life, activities of daily living and possibilities (employment and volunteering)
  - If it’s really a side effect
  - What the future holds

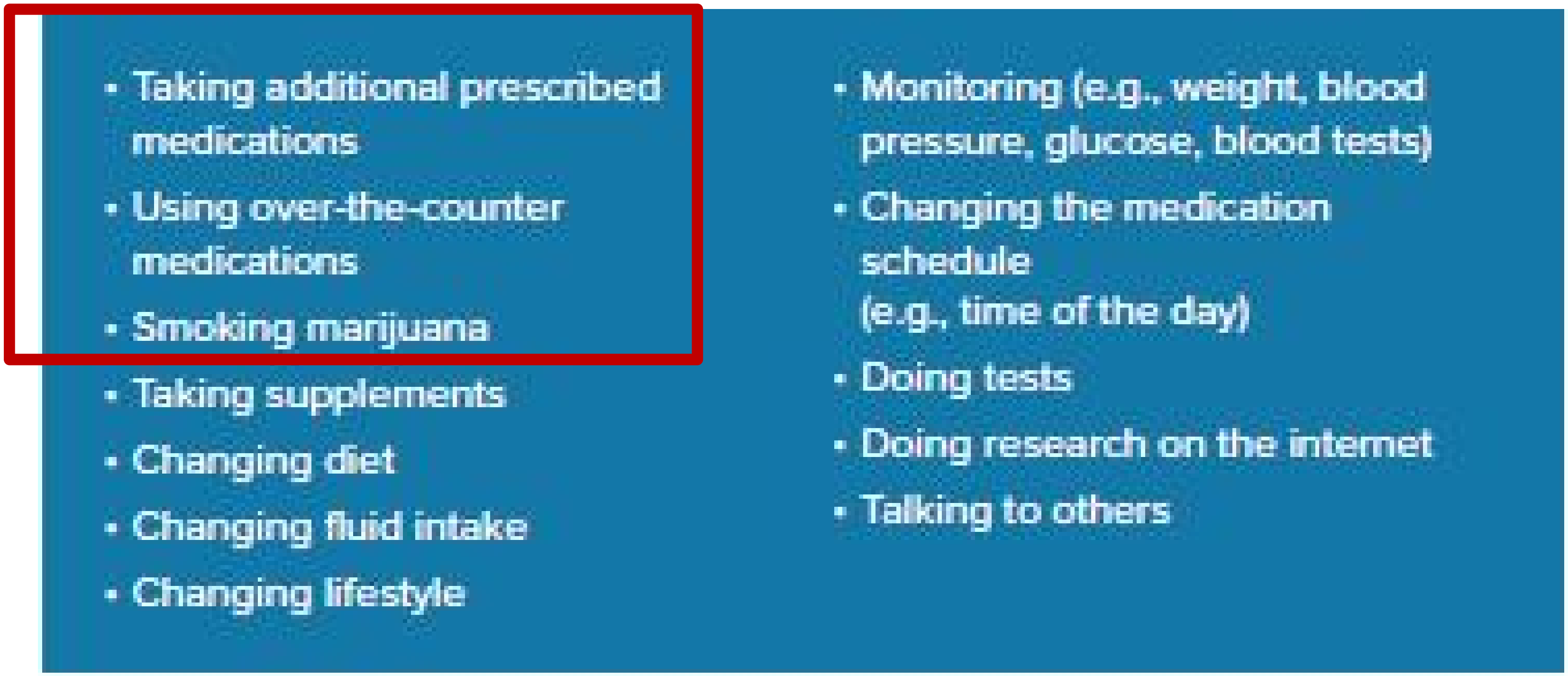
THE EXPERIENCE | Living with

- Living with limitations
  - Physical (pain, limits, fatigue)
  - Mental (concentration and memory)
  - Fonctional
    - Activities and movements (space, distance, locations)
    - Impact on freedom and isolation

Well I don’t go out that much unless there’s a bathroom nearby. Um, the heart palpitations, I, I walk a lot. Uh, but it’s always close to home. It has a big impact on my life. Uh, I can’t do what I used to do.

THE EXPERIENCE | Dealing with

- Management of side effects – « never completely managed »
  - Take charge, make a plan, find strategies



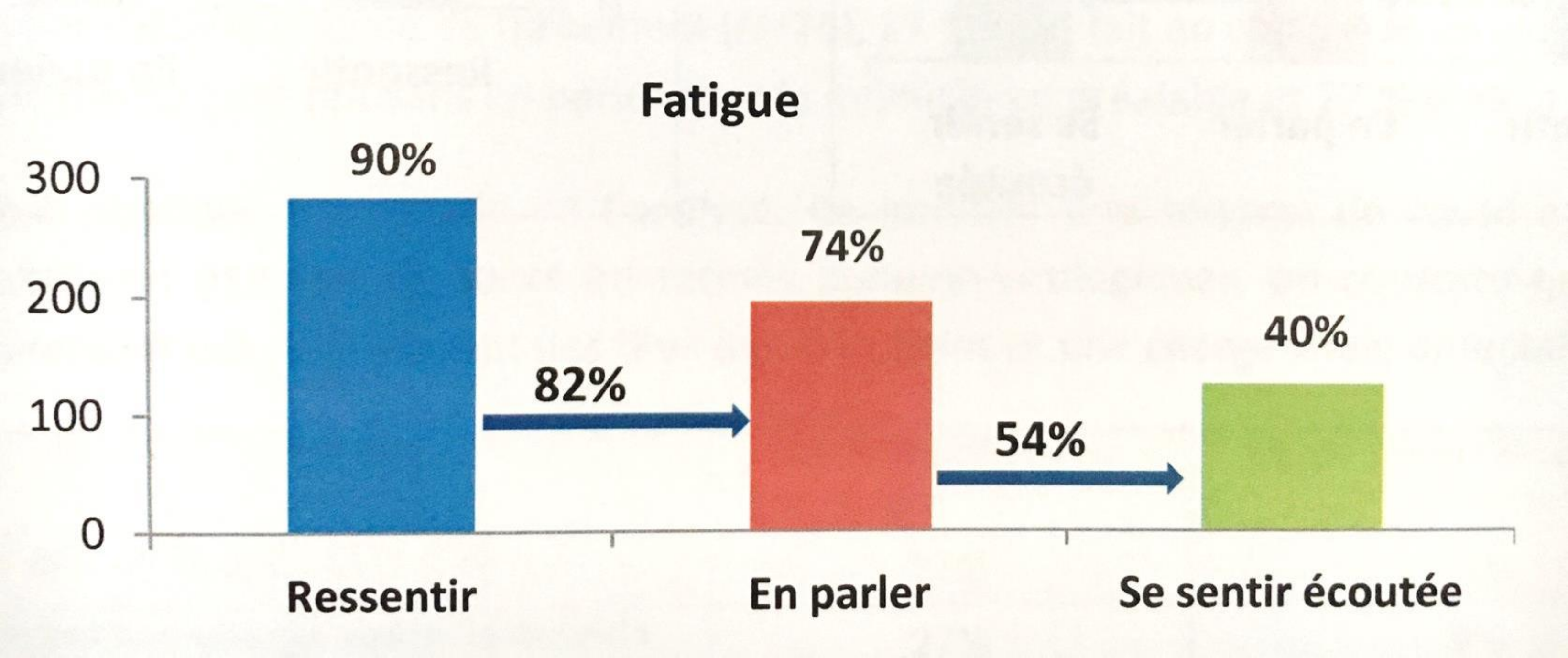
- Taking additional prescribed medications
- Using over-the-counter medications
- Smoking marijuana
- Taking supplements
- Changing diet
- Changing fluid intake
- Changing lifestyle
- Monitoring (e.g., weight, blood pressure, glucose, blood tests)
- Changing the medication schedule (e.g., time of the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

THE EXPERIENCE | Dealing with

- Management of the treatment
    - Continue – Stop – Change
    - What are reasons and objectives?
    - What are the fears and risks?
- Management of the physician (main issue)
    - Importance and recognition
    - Listening and management
    - Types of responses
        - The problem is you (life habits, attitudes, age)
        - The problem is in your head
        - « If it’s not broken, don’t fix it »
        - Treatment optimism (viral load)
        - A question of life and death

THE EXPERIENCE | Dealing with

- Management of the physician (main issue)
  - Enquête Ève (2015) (n=315 women living with HIV in France)



THE CONNECTIONS

People

- Medical specialists and specialized health care providers
- Peers (sources of information, support, and advice)

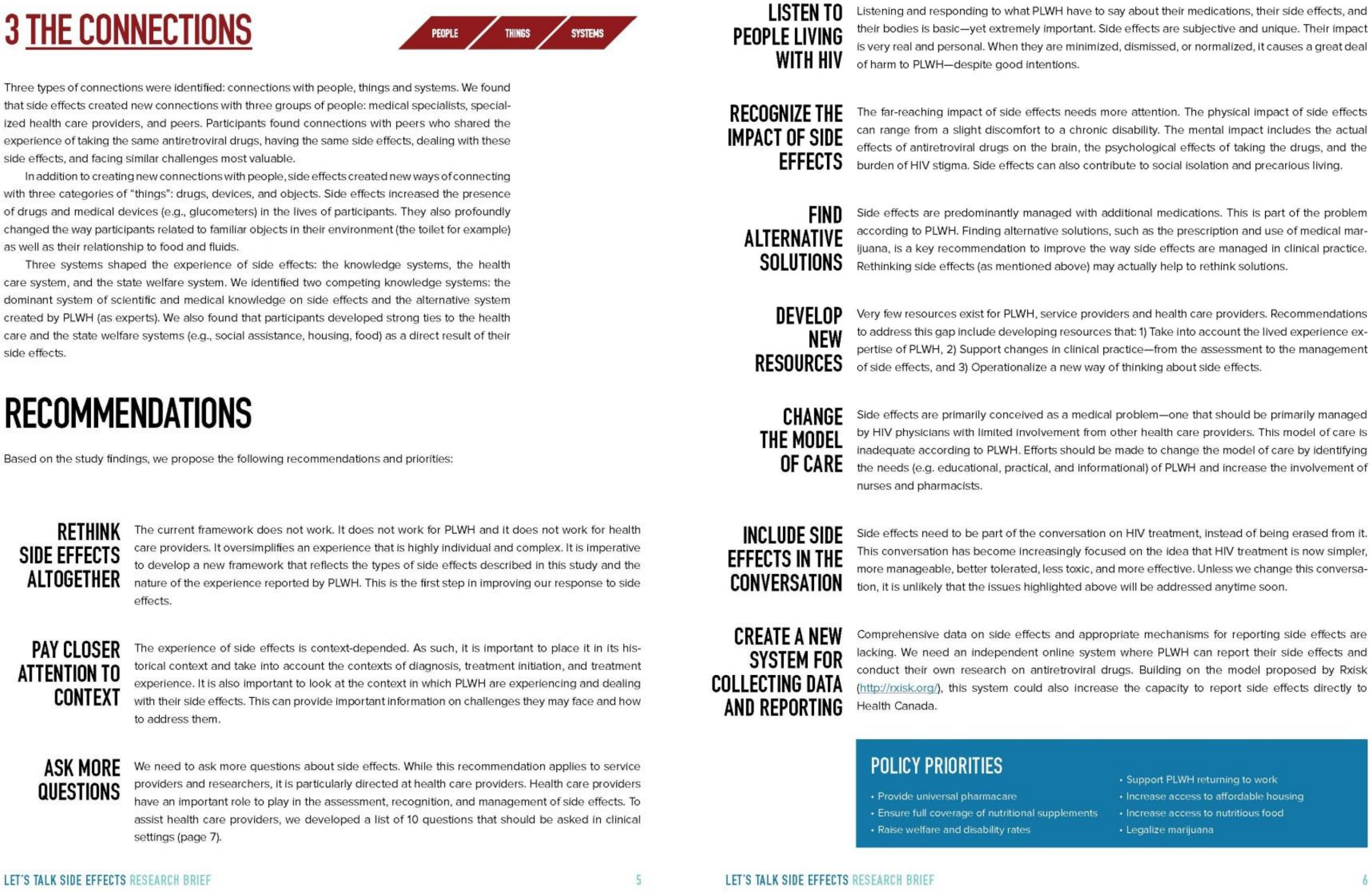
Things

- Medications (pill poppers) and substance (cannabis)
- Devices (glucometer), food, liquids and objects (toilet)

Systems

- Knowledge systems – dominant and alternative
- Health care system
- Welfare

RECOMMENDATIONS



3 THE CONNECTIONS

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-depended. 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).

LET'S TALK SIDE EFFECTS RESEARCH BRIEF 5

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

LET'S TALK SIDE EFFECTS RESEARCH BRIEF 6

RECOMMENDATIONS

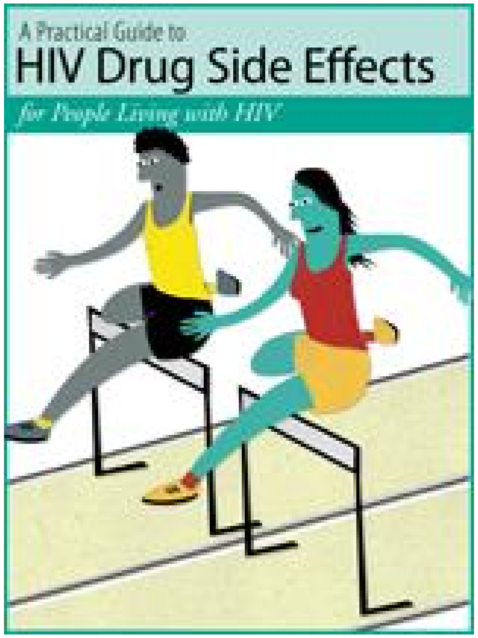
- Rethink side effects
- Pay closer attention to context
- Ask more question →
- Listen to PLWH
- Recognize the impact of side effects
- Find alternative solutions (cannabis)
- Develop new resources
- Change the model of care
- Include side effects in the conversation
- Create a new system for collecting and reporting

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?

RESOURCES

- CATIE
- Practical guide to HIV drug side effects



My Health Map

1. Name

2. Date

3. How am I feeling?

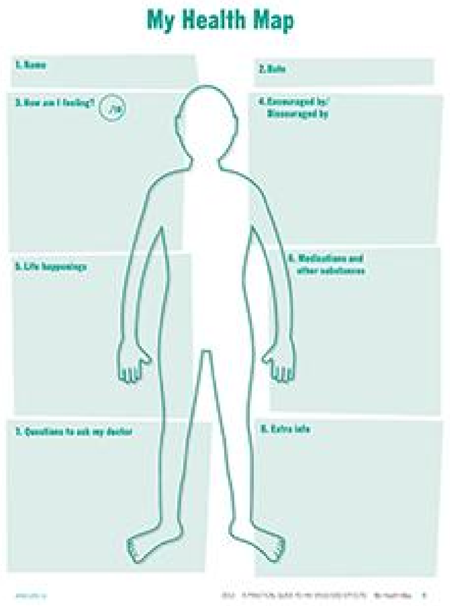
4. Encouraged by/Discouraged by

5. Life happenings

6. Medications and other substances (herbal therapies, vitamins, marijuana, alcohol, etc.)

7. Questions to ask my doctor

8. Extra info



My Health Map

1. Name

2. Date

3. How am I feeling? /10

4. Encouraged by/ Discouraged by

5. Life happenings

6. Medications and other substances

7. Questions to ask my doctor

8. Extra info

RESOURCES

- ICW
- Body mapping project
- Project report
  - Recommendations

Inclusion of women in research

More research on « real life » side effects

Greater access to plasma concentration analysis

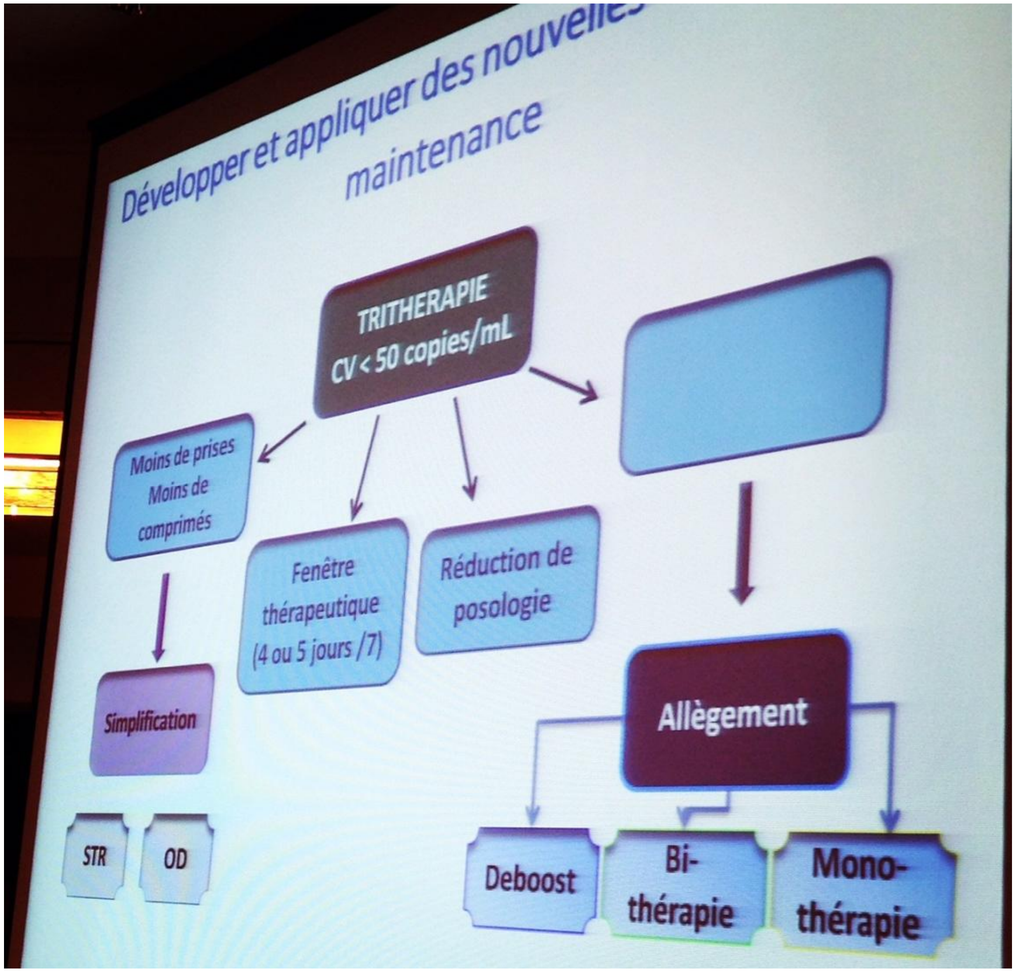
Improved care and support for women who report side effects

Increased support to access to healthy food, affordable housing, social assistance, and programs that covers the costs of supplements, etc.

Opportunities to support each other and share their experiences with others – AND their knowledge of side effects (and ways of dealing with them)

NEXT STEPS

- Treatment simplification (Journée québécoises du VIH 2016)



Développer et appliquer des nouvelle
maintenance

TRITHERAPIE
CV < 50 copies/mL

Moins de prises
Moins de comprimés

Fenêtre thérapeutique
(4 ou 5 jours /7)

Réduction de posologie

Simplification

STR

OD

Allègement

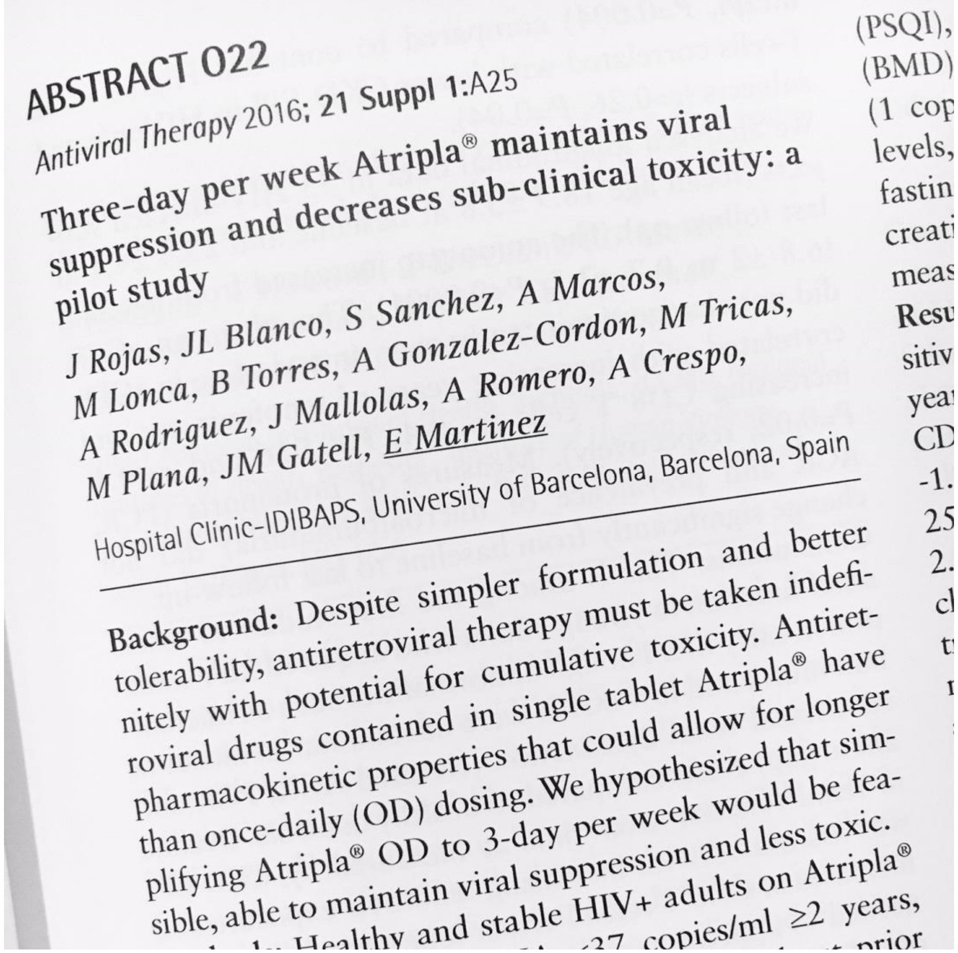
Deboost

Bi-thérapie

Mono-thérapie

NEXT STEPS

- Treatment simplification (International Workshop on AE 2016)



ABSTRACT O22

Antiviral Therapy 2016; **21 Suppl 1:**A25

Three-day per week Atripla® maintains viral suppression and decreases sub-clinical toxicity: a pilot study

J Rojas, JL Blanco, S Sanchez, A Marcos, M Lonca, B Torres, A Gonzalez-Cordon, M Tricas, A Rodriguez, J Mallolas, A Romero, A Crespo, M Plana, JM Gatell, E Martinez

Hospital Clínic-IDIBAPS, University of Barcelona, Barcelona, Spain

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Background: Despite simpler formulation and better tolerability, antiretroviral therapy must be taken indefinitely with potential for cumulative toxicity. Antiretroviral drugs contained in single tablet Atripla® have pharmacokinetic properties that could allow for longer than once-daily (OD) dosing. We hypothesized that simplifying Atripla® OD to 3-day per week would be feasible, able to maintain viral suppression and less toxic.

Healthy and stable HIV+ adults on Atripla® <37 copies/ml ≥2 years,

FOR MORE INFO

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Abstract
Despite the availability of new antiretroviral drugs and the simplification of treatment options, side effects continue to affect people living with HIV. In this paper, we present the findings of a grounded theory study designed to gain a critical understanding of the experience of side effects. Three main categories emerged from the data: the side effects, the experience, and the connections. The first category suggests that we need to change how we think about side effects in order to take into account the context in which they are experienced as well as the types and nature of side effects. The second category puts forward the idea that the experience of side effects is composed of three interrelated processes: becoming with, living with, and dealing with. Finally, the third category points to new connections that are formed with people, things and systems in the presence of side effects.

Mots clés adverse effects, antiretroviral, ART, grounded theory, HIV, side effects, toxicity

"So far it's been choosing which side effects I want or I can deal with": A grounded theory of HIV treatment side effects among people living with HIV

MARILOU GAGNON & DAVE HOLMES

Introduction

Despite the availability of new (and supposedly less toxic) antiretroviral drugs in industrialized countries and the simplification of treatment options (i.e., all-in-one combination tablets such as Atripla®), 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, although at present, it remains difficult to determine exactly how many people experience side effects and what side effects are most commonly reported.[2] 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, distal sensory peripheral neuropathy, cognitive deficits, and bone loss.[2] In addition to the common side effects listed above, each antiretroviral drug currently available has a unique side effect profile and a comprehensive list of potential drug-drug interactions.[4]

The experience of developing and not being able to manage

2016: Vol.8, Numéro 1/Vol.8, Issue 1 APORIA 19

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Original article

Body–drug assemblages: theorizing the experience of side effects in the context of HIV treatment

Marilou Gagnon* RN PhD **and Dave Holmes**† RN PhD
*Associate Professor, and †Full Professor, School of Nursing, Faculty of Health Sciences, University of Ottawa, Ottawa, ON, Canada

Abstract Each of the antiretroviral drugs that are currently used to stop the progression of HIV infection causes its own specific side effects. Despite the expansion, multiplication, and simplification of treatment options over the past decade, side effects continue to affect people living with HIV. Yet, we see a clear disconnect between the way side effects are normalized, routinized, and framed in clinical practice and the way they are experienced by people living with HIV. This paper builds on the premise that new approaches are needed to understand side effects in a manner that is more reflective of the subjective accounts of people living with HIV. Drawing on the work of Deleuze and Guattari, it offers an original application of the theory of 'assemblage'. This theory offers a new way of theorizing side effects, and ultimately the relationship between the body and antiretroviral drugs (as technologies). Combining theory with examples derived from empirical data, we examine the multiple ways in which the body connects not only to the drugs but also to people, things, and systems. Our objective is to illustrate how this theory dares us to think differently about side effects and allows us to originally (re)think the experience of taking antiretroviral drugs.

Keywords: antiretroviral, ART, assemblage, Deleuze and Guattari, HIV/AIDS, side effects.

> The day after I took the medication. Like, my body was like, 'What is this?' You know, it just told me like something's different. And I noticed it, it just… like my ear would start to ring or I would see little spots or something, but it wasn't me, it was my body telling me, 'This is something different and we have to deal with it somehow', you know? It was weird and I didn't like it.

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Introduction

Despite the availability of new (and supposedly less toxic) antiretroviral drugs in industrialized countries and the simplification of treatment options (i.e. all-in-one combination tablets such as Atripla®), side

250

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Let's Talk
SIDE EFFECTS
Research Brief

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Dr. Dave Holmes, RN, PhD

Questions?

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