

CASES IN GLOBAL HEALTH DELIVERY

GHD-038 DECEMBER 2017

Improving Mental Health Services for Survivors of Sexual Violence in the DRC

In 2016, Karin Wachter was asked to reflect on a study she had contributed to in her previous role at the International Rescue Committee (IRC). The IRC had begun its work in the Democratic Republic of Congo (DRC) by building local organizations' capacity to support survivors of gender-based violence and eventually was running complex studies with researchers in Johns Hopkins University's Applied Mental Health Research Group (AMHR). The IRC and AMHR conducted a randomized controlled trial (RCT) of a clinical mental health treatment and showed that a majority of female survivors of sexual violence in the DRC who received the intervention exhibited a reduction in symptoms of depression, anxiety, and post-traumatic stress disorder, as well as improved functioning. The study was an important contribution to the lean body of research on mental health in conflict settings. The group's simultaneous RCT testing the impact of an economic empowerment program on survivors found no significant mental health effects.

Wachter considered the resources the IRC had invested in terms of staff time and funding. *Had the studies been worth it?* What would be the long-term impact for women who continued to live in communities impacted by armed conflict?

Overview of the Democratic Republic of the Congo

The DRC was the second-largest African country, covering an area about two-thirds the size of Western Europe (Exhibit 1). In 2013, French was the official language; however, 240 languages were spoken nationwide.

History

Portuguese traders arrived in what is now the DRC in the 1480s and found an abundance of natural resources and people they soon put to work for them. According to historian Dan Snow, "They did their utmost to destroy any indigenous political force capable of curtailing their slaving or trading interests."²

C. Nicholas Cuneo, Julie Rosenberg, Amy Madore, and Rebecca Weintraub prepared this case with assistance from Kelly Holz for the purposes of classroom discussion rather than to illustrate either effective or ineffective health care delivery practice.

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In 1885, King Leopold II of Belgium created a vast private empire he called the Congo Free State.³ The bicycle and auto industries were beginning to explode in the West, which created high demand for Congo's rubber. Leopold brutally enslaved men to harvest the rubber while their wives were held captive and often tortured. Outspoken tribal leaders were killed, education was denied, and millions died. International criticism eventually forced Leopold to cede control of the territory to Belgium's civil government, which renamed the area Belgian Congo in 1908.⁴ Black Congolese remained oppressed. Decades later, among the 5,000 government jobs, just three were held by Congolese; there was not a single Congolese lawyer, doctor, economist, or engineer.²

In 1960, the Congo Free State gained independence from Belgium and became the Republic of Congo. Five years later, national defense leader Joseph-Désiré Mobutu staged a coup.⁵ A constitutional referendum changed the country's name to Democratic Republic of Congo. Mobutu consolidated power, renamed the country the Republic of Zaire, and launched a campaign to uproot colonial influence, expelling European investors and nationalizing many foreign-owned assets.⁶ During his 32-year dictatorship, Mobutu embezzled millions in public funds while most Zairians lived in abject poverty. The West did little to intervene as long as resources continued to flow.

In 1994, the genocide of the Tutsi in Rwanda led to the deaths of an estimated 800,000 people in 100 days. Many of those who participated in the genocide fled to eastern Zaire, organized within refugee camps, and continued to carry out atrocities. In August 1996, ethnic and linguistic differences fueled ongoing tensions, launching the First Congo War.⁷ The conflict ended in 1997, when Mobutu fled Zaire and rebel army leader Laurent-Désiré Kabila declared himself president. Kabila changed the country's name back to Democratic Republic of Congo.

The Second Congo War began in 1998, when militias in eastern DRC formed a rebel army to oppose Kabila. A multinational conflict among approximately 20 different armed groups ensued and was fought almost entirely in the DRC.² The DRC's vast supplies of coltan, a mineral used in mobile phones, and other natural resources added urgency to the conflict. Widespread attacks on communities, looting, conscription into armed groups, rape, and murder drove survivors to the jungle, where they faced starvation and disease. Millions of people died, and millions more were displaced. In response, the United Nations (UN) began a DRC stabilization mission in 1999.⁸

When President Kabila was assassinated in 2001, his son, Joseph Kabila, took office. His regime was as oppressive as his father's. The Second Congo War ended in 2003; however, key infrastructure had collapsed and fighting continued among rebel groups, community militias, the national army, and the UN in the eastern provinces of South Kivu and North Kivu.⁹ Roads no longer linked to major cities, and public services were nearly nonexistent.

Economy

In terms of gross national income per capita (USD 414 in 2013), the DRC's people were some of the poorest in the world. Safety concerns (e.g., rebel attacks) in resource-rich rural areas and limited jobs drove many Congolese to cities.¹⁰ More than one-third of people age 15 or older were illiterate, and few Congolese had a college or university degree.¹¹

From 1988 to 2001, gross domestic product (GDP) fell almost every year.¹² Economic growth reached 5.8% after the Second Congo War but fell again with the 2008 global financial crisis. The DRC reconfigured its macroeconomic policies to qualify for financial aid and debt relief from the International Monetary Fund and World Bank. It received USD 736 million in humanitarian aid in 2013, making it one of the top five recipients globally.¹⁰

INDICATOR		YEAR
UN Human Development Index Ranking	186 (out of 187)	2013
Population (thousands)	74,877	2014
Urban population (%)	42	2014
Improved water source (% of population)	51.8	2013
Poverty rate (% living under USD 1.90 /day, 2011 PPP)	77.1	2012
Gini index	42.1	2012
GDP per capita in PPP (current international \$)	784.4	2015
GDP per capita (current USD)	413.7	2013
Literacy (total/female/male)	63.8/50/78.1	2015

Health in the DRC

Average life expectancy in the DRC hovered at 46–47 years during the 1980s and 1990s.¹³ In 2010, malaria, diarrheal diseases, and malnutrition were the leading contributors to years of life lost due to premature death, while iron-deficiency anemia, major depressive disorder, and lower back pain were the top causes of years lived with disability.¹⁴ Mental health issues cost the DRC an estimated 2,561 disability-adjusted life years (DALYs) per 100,000 population in 2014.¹⁵

Acts of gender-based violence (GBV), including sexual violence, * spiked dramatically during the Congo Wars and remained high over the next two decades; interpersonal violence was the fastest-growing cause of premature death. In eastern DRC in 2010, an estimated 39.7% of women and 23.6% of men in conflict-affected areas had experienced conflict-related sexual violence at some point. Many survivors had mental health issues: around 40% had major depressive disorder, half had post-traumatic stress disorder (PTSD), and 16% reported a past suicide attempt (see **Exhibit 2** for mental health definitions, global burden, and treatments). Total Porty-two percent of women in the DRC reported experiencing intimate partner violence.

Social stigma associated with sexual violence could have devastating consequences for survivors, including rejection by their families and communities.^{19–21}

Health System

In 1975, the government decentralized primary health care and began working with faith-based organizations to co-manage health facilities. By 2013, religious organizations operated approximately one-third of the country's health facilities.²²

The Ministry of Public Health (MoPH) organized local service delivery with "health zones": rural zones covered 50,000–100,000 people, and urban zones covered 100,000–250,000 people. Health zones and facilities were relatively autonomous and relied on user fees to pay operating costs.

^{*} Compiled by case writers using data from UN agencies, World Bank, and the IMF.

[†] Any act based on gender that resulted in or was likely to result in a person's physical, psychological, or sexual harm, including but not limited to intimate partner violence, rape, early marriage, and trafficking. ¹⁶

In 2013, average annual household spending on health care was USD 110 for outpatient services, USD 38 for hospitalizations, and USD 58 for other health expenses (e.g., medicines, first-aid supplies). Urban households spent an average of three times as much (USD 376) as rural households (USD 128).²³

Health System and Epidemiologic Indicators[‡]

INDICATOR		YEAR
Average life expectancy at birth (total/female/male)	52/54/51	2013
Maternal mortality ratio (per 100,000 live births)	693	2015
Under-five mortality (per 1,000 live births)	98	2015
Infant mortality rate (per 1,000 live births)	75	2015
Vaccination rates (% of DTP3 coverage)	80	2015
Undernourished (%)	24.2	2010
Adult (15–49 years) HIV prevalence (per 100,000)	1,000	2014
HIV antiretroviral therapy coverage (%)	18	2013
Tuberculosis prevalence (per 100,000)	532	2014
DOTS coverage (%)	100	2006
Malaria cases (per 1,000)	92.6	2013
Government expenditure on health as % of total	12.9	2013
government expenditure		
Government expenditure on health per capita	14/8	2013
(PPP international dollars/USD)		
Total health expenditure per capita (current USD)	16	2013
Physician density (per 10,000)	.91	2009
Nursing and midwifery density (per 10,000)	9.6	2009
Number of hospital beds (per 10,000)	8	2006

Mental Health Service Delivery

The government spent 1% of its health budget on mental health in 2012.²⁴ The MoPH's National Mental Health Program, established in 1999, aimed to address the absence of mental health care in the DRC. It planned to decentralize mental health services from the country's six mental health hospitals by integrating them into primary care; however, as of 2013, it had not been implemented.

In the early 2000s, some local Congolese organizations provided *psychosocial support*—a broad term for interventions designed to promote psychological and social well-being, including active listening, action planning, and referral to other services²⁵—for survivors of sexual violence.^{26,27} Psychosocial support programs typically were not standardized or considered mental health treatment.

While there were efforts to raise awareness of the existence and effects of sexual violence and available support services, an international NGO worker said, "True prevention of conflict-related sexual violence would have meant ending fighting between the warring factions."

In 2013, there was no referral system for primary health care facilities to send patients to mental health care providers.²⁸ Primary care physicians could prescribe psychiatric medications, but patients from rural areas who received prescriptions from urban providers had difficulty refilling them near home.²⁸

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[‡] Compiled by case writers using data from WHO, World Bank, PEPFAR, UNICEF, WHO, GAVI, STOP TB, and UNFPA. Data represent latest available as of 2015.

Only three Congolese universities hosted faculties of psychology, and two of those were primarily "theoretical," not clinical.²⁹ Mental health jobs were scarce. In 2014, there were 0.10 psychiatrists and 0.24 psychiatric nurses per 100,000 people in the DRC, approximately one for every 1 million.³⁰ There were fewer social workers, and only 11 doctoral-level clinical psychologists. Most mental health professionals worked in cities, away from the conflict.¹¹ Some of the DRC's six mental health hospitals lacked basic medications and equipment.²⁵ Its only outpatient mental health facility was in the country's capital, Kinshasa.¹¹

Many people in rural areas believed that witchcraft or supernatural elements caused mental disorders. As a result, sometimes families consulted traditional healers or priests for care, whose treatments included exorcism ceremonies and the use of medicinal plants.¹¹ Many Christian Congolese believed prayer could resolve mental health issues.³¹

Mental Health Research in Low- and Middle-Income Countries

Evidence-based treatments for mental health symptoms related to sexual violence had been shown to reduce PTSD, anxiety, fear, and/or depression in survivors. Researchers also had demonstrated that behavioral interventions reduced PTSD symptoms more than supportive counseling did.³² However, there was little research on the use of such treatments in low- and middle-income counties (LMICs), especially conflict-affected settings. A 2007 study revealed that only 10% of 11,501 mental health RCTs had been conducted in LMICs, and two-thirds of them had taken place in China.³³ Mental health research in LMICs required culturally relevant clinical definitions, and ethical considerations presented an obstacle: financial or other rewards for participation were more likely to be coercive for study candidates living in poverty, who were especially vulnerable if their capacity was impaired due to their illness.³⁴

In 2000, US-based researchers Paul Bolton and Judith Bass teamed up with USAID and World Vision to conduct the first mental health RCT in Sub-Saharan Africa (see Exhibit 3 for more information about RCTs).³⁵ In 2004, Bolton established the Applied Mental Health Research Group (AMHR), an association of mental health faculty and researchers at Boston University. The group aimed to help public and nongovernmental providers identify and tackle mental health problems through qualitative research, intervention design, and program monitoring and evaluation.

The International Rescue Committee

The International Rescue Committee (IRC) was a humanitarian organization founded in the 1930s to "restore health, safety, education, economic wellbeing, and power to people devastated by conflict and disaster." In 2002, a senior director in the IRC's headquarters in New York supervised each of four technical units (Health; Children and Youth; Economic Recovery and Development; and Governance and Rights). The IRC also provided emergency response and advocacy services. The organization had a reputation for being supportive of research including studies of war-affected populations in the early 2000s.

Early Response to Gender-Based Violence

In the late 1990s, in part as a response to the ongoing humanitarian crisis and reports of so-called "rape camps" in war-torn Yugoslavia, "the humanitarian community and academics woke up to women's roles and experiences in displacement," an IRC staff member said. "There were strong advocates and programmatic people within the IRC who said that this is what we needed to be looking at, and they knew how to build organizational focus and commitment to it."

In 1996, the IRC received GBV funding from the UN High Commissioner for Refugees (UNHCR), which it used to start a program for Burundian refugees in Tanzania. It created drop-in centers for GBV survivors and trained women in refugee camps to staff them. Centers provided basic supplies and case management to survivors, including legal representation, counseling, and medical referrals (e.g., for STI testing and treatment).³⁷ "We did a lot of listening to people to identify their needs and then tried things out. We were running and creating it as we went," an IRC staff member said.

That year, the IRC started working in the DRC. Its main office was in Bukavu, the capital of the eastern South Kivu province. It initially focused on providing emergency health care for people affected by the conflict in collaboration with the MoPH and on supporting local nongovernmental organizations (NGOs) and community-based organizations (CBOs). Many CBOs had formed before the Congo Wars to close public service gaps. They tended to be less structured than NGOs; many were groups of women who volunteered to support survivors of violence with food, cooking supplies, and clothing. CBOs often received subcontracts from larger CBOs and NGOs or generated their own income through farming, selling crafts, and other activities.

Concerned about the reliability of available data guiding its efforts, the IRC also collaborated with epidemiologists to conduct the first scientific mortality survey in the DRC. Preliminary results revealed 1.7 million more deaths than originally estimated for the period August 1998–May 2000, many stemming from the conflict's impact on the frail health system.³⁸ Media coverage led to unprecedented interest in the DRC and a surge in donations. Aid from the US alone increased 26-fold.

In 1998, the IRC published a report documenting lessons and challenges from its Tanzania program,³⁹ and over the next three years, established new GBV projects in other refugee camps and post-conflict settings in Congo-Brazzaville, Sierra Leone, Kosovo, East Timor, and Pakistan.³⁷ In 2001, GBV project staff worked with the UN to document recommendations for GBV prevention and response. They emphasized the need for better program monitoring and evaluation, increased security for staff, engagement of men in prevention, community awareness education, and closer inter-agency coordination.^{40,41}

The IRC steered away from providing clinical mental health treatment. "It wasn't because we didn't think mental health programming was important," an IRC director said. "In fact, we thought it was so important that licensed mental health specialists should be doing the work. We didn't want to do it poorly."

Establishing a GBV Program in the DRC

In 2002, the IRC received USD 500,000 from the US Agency for International Development (USAID) to build local organizations' capacity to respond to GBV in eastern DRC. The IRC hired Xavier Bardou, a French national with communications training and experience managing projects in neighboring Burundi, and Karin Wachter, an American with a master's degree in international education. "The IRC was the organization doing the type of work I wanted to do: addressing violence against women in emergency and complex humanitarian settings," Wachter said. Bardou and Wachter hired Congolese staff, including Julie Gubanja and Marin Honorine Chiribagula, who were responsible for helping local organizations develop human resource capacity and financial management systems with an eye to strengthening organizational capacity to support GBV survivors. Around the same time, the IRC moved GBV out from under the Health Technical Unit and created a new and separate GBV Technical Unit.

The DRC GBV team solicited proposals from local NGOs to connect survivors to health, psychosocial, and legal support services; support economic empowerment programs; strengthen referral systems and inter-agency collaboration to improve the security and protection of women and girls; and raise local and international awareness of GBV.

The GBV team created and chaired a task force, including IRC staff and local community members, to evaluate the dozens of proposals they received. "Local organizations were already doing a lot to take care of people experiencing violence," Wachter said. "When we issued the call for proposals, many of them saw an opportunity to frame their work in a new way. Some NGOs had microfinance projects, for example, and they started to think about what it would mean to do microfinance specifically with women who were survivors of sexual violence." After full-day site visits with promising applicants, the task force selected seven NGOs to receive one-year renewable grants.

The NGOs recruited existing or new staff members to be psychosocial assistants (PSAs) and decided how much to pay them. The IRC trained PSAs to provide psychosocial support and case management services to GBV survivors. The GBV team's initial focus was the quality and accessibility of services for survivors. Once trained, PSAs counseled women one-on-one in *maisons d'ecoute* ("listening centers"), private spaces in the community where survivors could talk confidentially about their experiences, discuss coping strategies, receive emotional support, and obtain referrals to other resources. While any GBV survivor was eligible for services, survivors of conflict-related sexual violence were the IRC's priority population.

PSAs used paper forms to track sessions, which the NGOs compiled to submit quarterly to the IRC. "Tracking was very difficult," Wachter said. "Double-counting of repeat participants was a big problem; we couldn't be confident in the numbers we received." The IRC sent staff to the field to review records and help address errors when they identified inconsistencies or gaps in reports.

The number and dynamism of CBOs in eastern DRC compelled the GBV team to design and issue a second call for proposals. The team selected five CBOs, which received smaller grants to support women's livelihood activities.

By the second year, the GBV program had grown to include 16 staff. "The work was incredibly rewarding, extremely fast-paced, and often stressful," Wachter reflected. "You worked around the clock ... The colleagues I met at IRC GBV conferences were working in either post-conflict settings or protracted refugee situations—places where people were returning and rebuilding. At the time, it felt like the issues we were dealing with in the DRC—an active war zone—were starkly different."

The GBV team shared information and resources with the IRC's health team whenever possible; however, many of the health zones the IRC worked in did not overlap with the GBV catchment area.

Creating a Functionality Assessment Tool

In 2005, USAID funded AMHR to help the IRC's GBV team strengthen program monitoring and evaluation. The IRC saw the project as an opportunity to improve program quality and ensure GBV services were meeting women's needs. Bolton, Bass, and clinical psychologist Laura Murray learned that PSAs had little oversight and their client records were insufficient to support monitoring and evaluation. They recommended that AMHR help the IRC identify the major psychosocial issues facing survivors of GBV and develop a culturally relevant tool to record baseline functioning. The existing tools, Bolton noted, "focused on the individual's perception of their symptoms rather than the effect of their symptoms on their day-to-day lives. It's nice if they can reduce patients' symptoms, but the main outcome of psychosocial and other mental health programming should be restored function—the ability to take care of their families and perform everyday tasks such as cleaning, cooking, and working their land."

While Wachter agreed that program monitoring was inadequate, she was initially skeptical of AMHR's involvement. "When you hear from US-based academics that they're going to figure out what the psychosocial needs are on the ground, it's like, 'We're pretty sure we know what they are—we speak to people constantly and feel pretty in tune,'" she said. After a few more discussions with Bolton and his team,

Wachter grew confident that they had their partners' and clients' interests in mind and convinced that academic research could improve work in the DRC by strengthening monitoring and evaluation.

In January 2006, Wachter was promoted to GBV regional technical adviser and relocated to Burundi. That month, the IRC published the results of the mortality study it had done with its research partners in *The Lancet*: 3.9 million people had died as a result of the conflict between 1998 and 2004, the majority from preventable infectious diseases and malnutrition, not violence.⁴²

Wachter continued to advise the DRC GBV program, returning monthly or bimonthly for two-week visits. "There was a lot of IRC staff turnover, so even though as technical adviser I was meant to backstop the program, I spent many of my visits helping to run it," she said. In February, AMHR—which Bolton moved to Johns Hopkins University when he took a new position there—returned to eastern DRC to conduct a qualitative study of day-to-day functioning. "By the time Paul Bolton arrived," Wachter said, "Many on our team saw him as a committed partner."

The IRC helped identify 11 people for AMHR to train in qualitative interviewing methods and data analysis over two days. Following the training, the interviewers traveled to villages and asked a convenience sample of 34 men and women about problems in their communities. Respondents were most concerned with hunger and malnutrition, followed by theft and sexual violence (see **Exhibit 4** for participant responses). AMHR spent another day training the interviewers to explore these concerns in greater detail with local leaders.

AMHR also had interviewers collect data to inform a gender-based functionality assessment tool for evaluating program participants. The interviewers asked participants what it meant for men and women to function normally in their communities.

In the middle of the study, the IRC evacuated the expatriate research team in advance of a UN voluntary arms collection as a safety precaution. It had a difficult time finding someone on the ground with the data entry and analysis skills to manage the research database. The person they eventually hired and trained passed away shortly after taking the role, so this work was delayed while the IRC looked for a new person to fill the position.

Later that year, leaders at IRC headquarters established a Research, Evaluation, and Learning (REL) Unit. Its purpose, as one leader described it, was "to make the IRC's work more evidence-based."

In late 2007, Bolton, Bass, and Murray worked closely with IRC staff to finalize and pilot the functionality tool (see **Exhibit 5** for questions, **Exhibit 6** for responses), which included visual aids to help clients with low literacy express their symptoms. During this time, the IRC introduced "quality checklists" to standardize and improve PSA performance and established monthly reporting requirements for partner NGOs. In early 2008, the IRC trained PSAs to use the functionality tool. They assessed clients at intake, during the psychosocial intervention, and six months following the intervention.

Wachter and her colleagues were excited to have the new tool. "I think there was a lack of appreciation on our end, at first, for what it means to systematically assess well-being," she said, "and perhaps a lack of appreciation on their end for the depth of knowledge organizations on the ground already had."

Programming Changes

Over time, the IRC narrowed the focus of its NGO partnerships to psychosocial support and standardized its definition of case management and psychosocial support services (see Exhibit 7). It reduced the number of grants it administered, retaining organizations with the best results, and increased technical

assistance to partners. Spending on partner capacity building grew from 4% of the DRC GBV program budget to 15%. The rest of the budget covered operating costs, including salaries.

The IRC also began working with CBOs to incorporate psychosocial support and case management into their GBV programs. Every 10 months CBOs received around USD 3,000 to support their activities and USD 1,000 for advocacy campaigns (see **Exhibit 8** for an overview of IRC budget allocation changes). By the end of 2008, the IRC was working with 5 NGOs and 19 CBOs.

Learning from the Functionality Assessment Tool

In April 2008, Bolton and Danuta Lockett, a consultant to USAID, visited the DRC for one week. The IRC was managing and monitoring its partners more closely; better data collection and monitoring processes were in place; and the PSAs were using the functionality tool.

Bolton and Lockett interviewed PSAs and reviewed the functionality data they had collected. Compared with other trauma-affected populations AMHR had assessed, participants exhibited substantially higher rates of psychosocial problems and dysfunction. Most participants' symptoms and functioning reportedly improved with the GBV program; however, it was unclear if the improvement was a result of the intervention. They could not rule out other variables (e.g., the passage of time) as the source of improvement and wondered if having PSAs administer the tool biased responses.

In addition, PSAs identified several women with more severe and persistent mental health symptoms who had not improved. A PSA supervisor recalled, "We had been doing case management with these women for at least 10 years, and we began to realize through the functionality tool that some of them still had not recovered from their trauma." They noted the shortage of mental health referral options in the region and expressed a desire for training to treat more complicated cases.

Bolton suggested identifying an evidence-based clinical intervention designed specifically for PTSD and other symptoms stemming from sexual violence and implementing it as an RCT to test its effectiveness in the DRC.

The IRC had recently hired a new Research, Evaluation, and Learning Unit director, Jeannie Annan, who had a PhD in counseling psychology and experience with clinical care, RCTs, and humanitarian aid. She was drawn by the opportunity to "bridge research and practice." Bolton recalled Annan's hire as a turning point: "It's one thing to have some academic person from Hopkins telling you that you should do something. It's another thing to have someone on the inside telling you the same thing."

Randomized Controlled Trials

In September 2009, the IRC changed the GBV Technical Unit's name to Women's Protection and Empowerment Technical Unit, and Wachter transitioned into a senior technical adviser role with the new unit at IRC headquarters. The program head in the DRC at the time flew to New York to meet with Wachter, Annan, Bolton, and Bass about next steps for a possible RCT. "We wanted to use research to advance the field and to see how evidence-based interventions would work in this context," Wachter said. The group agreed the IRC should consider a standardized clinical mental health intervention to help women who had not improved with psychosocial support. Bolton asked Bass to lead the study and submitted a grant proposal to USAID.

Bolton and Bass also raised the possibility of exploring the potential impact of economic empowerment on women's mental health and functioning. The correlation between poverty and mental health outcomes

was well established,⁴³ and limited published data on the effect of economic interventions on mental health were promising: in 2009, for example, researchers linked participation in a lending program in South Africa with decreased depressive symptoms.⁴⁴ Early data from the Village Savings and Loan Association (VSLA) program,⁴⁵ a USAID-funded economic and social empowerment intervention that the IRC was piloting with the London School of Economics in Burundi, showed greater financial decision-making authority among women reduced exposure to and acceptance of violence. It also showed a higher consumption of household goods relative to luxury goods.⁴⁶ Altogether, VSLA seemed to have a promising effect on economic outcomes (see **Exhibit 10** for theory of change), lifting twice as many families out of poverty as a control group, and it was relatively inexpensive to run.⁴⁷ Furthermore, women in the DRC consistently voiced the need for economic programs.

The IRC and AMHR chose VSLA for the DRC to generate evidence in support of VSLAs, which many countries were implementing but had not studied in relation to mental health outcomes. The IRC's VSLA manager in Burundi transferred to Bukavu in late 2009 to manage implementation in the DRC.

Senior IRC and AMHR leaders obtained input and buy-in from in-country staff—especially leadership—before planning the interventions. IRC country directors had considerable authority and autonomy; their support had been critical to implementing research projects in other units, such as health and governance. In April 2010, the IRC and AMHR hosted a three-day meeting in Bukavu. Attendees included Annan, Wachter, Bass, Women's Protection and Empowerment program staff (many of whom were new), and the North and South Kivu IRC provincial directors. The meeting was conducted mainly in English, and most attendees were not Congolese. Representatives from the IRC's local NGO partners did not participate.

Bass asked the IRC team to describe their work in the DRC, including the number of villages and women they served and the services they offered. "I wanted to get the lay of the land so that we could design the studies," she said. "I also wanted to hear from the field team what they were thinking, what capacity they had, and what capacity they wanted to build. Our hope was that by doing this, everyone would be on the same page and feel invested in the project."

Many IRC staff worried that the studies would draw resources away from existing clients and program operations. "The priority of the organization was responding to violence against women and meeting their needs," Wachter said. "There was this tension between wanting to put the program first and feeling excited about what the RCTs could do not only for the DRC but for IRC's GBV programming writ large." Staff also expressed concern about control group participants not receiving services. The researchers reassured them that the control group could have ongoing access to services as usual (individual psychosocial support) and that the interventions would be made available to them if they proved effective. "This helped the program staff become more comfortable with the idea, but the thought of withholding a service that might help someone still didn't feel good to them," Wachter said. The IRC country director for the DRC voiced support for the research and helped move the team forward.

Meeting participants agreed on the basic details of study implementation. They decided to conduct two parallel RCTs. One would compare the outcomes of women survivors of sexual violence receiving a group mental health intervention with the outcomes of women survivors of sexual violence receiving the IRC's individual psychosocial support and case management services. The other would study the impact of VSLA on mental health and on economic well-being (see **Exhibit 9** for detailed study objectives). Each study would compare an intervention group with a wait-listed control group sample. If the mental health intervention proved effective, VSLA participants would have the opportunity to enroll in it after the studies concluded. Subjects in the mental health intervention would be enrolled in VSLA following therapy, enabling the research team to explore both the independent effects of the mental health intervention and its

impact on VSLA participant retention and outcomes. The IRC and AMHR hypothesized improving social and economic functioning through the VSLA would indirectly improve mental health for survivors of sexual violence with high and persistent trauma symptoms (see **Exhibit 10** for theory of change). They also believed regular participation in a social group might confer additional mental health benefits to women.

USAID funded the mental health intervention and a portion of the VSLA study (approximately USD 1 million/year, 2010–2015), in addition to funding PSAs. AMHR requested additional support for the VSLA trial from the World Bank, which agreed to split the costs with USAID. AMHR was the primary recipient of both grants and disbursed funds to the IRC. "Johns Hopkins was not only our research partner, but also a funder and implementing partner," the VSLA manager said. "It was a unique arrangement for us."

The Interventions

Bolton and Bass were responsible for recommending an evidence-based mental health intervention to implement. They considered two options: interpersonal psychotherapy (IPT) and cognitive processing therapy (CPT). Interpersonal psychotherapy focused on treating depression by improving how patients communicated with and related to others and had performed well in clinical trials in Africa.⁴⁸ CPT was designed as a group therapy to help rape survivors confront and cope with memories and thoughts that triggered distress, fear, shame, and other debilitating feelings. In the US, licensed mental health professionals, trainees, and graduate students could learn to administer CPT during a two-day training and six months of consultation.

Bolton and Bass solicited advice from Debra Kaysen, a professor of psychiatry at the University of Washington who had experience conducting trials with CPT. Kaysen believed CPT was a good fit based on the symptoms women had reported during Bolton's initial qualitative study. She expressed some concern that it would be challenging to provide CPT in eastern DRC because most women were illiterate. In the US, an eighth-grade reading level was required for clients to receive CPT, and therapists were expected to have a master's level education. Bolton and Bass selected a specific type of CPT, cognitive processing therapy-cognitive, because it could be easily applied in a group setting (which would require fewer therapists and enable comparison with the group-based VSLA) and had proven effective for survivors of sexual trauma. CPT-cognitive also was easier to administer in a group setting than traditional CPT, which included a personal trauma narrative, and had great participant retention.⁴⁹ In addition, Kaysen explained, "We were thinking ahead to scale-up. A group intervention would make it much more feasible to reach a large number of people."

Kaysen adapted the CPT program for illiterate participants. "I had to think about which parts were important and which parts could be window dressing," she said. Adaptations included an initial one-on-one session to familiarize participants with CPT, oral completion of assignments, and simplification of concepts and materials to facilitate understanding and memorization.⁵⁰

Establishing strong routine supervision was a priority; several studies noted its role in the effectiveness of lay health workers delivering psychosocial and psychological interventions,⁵¹ and the IRC wanted to avoid worsening the mental health of women if PSAs delivered the treatment incorrectly. Between two and five Congolese supervisors with counseling experience, but no advanced mental health education, would be responsible for managing the PSAs through weekly phone or in-person meetings. AMHR hired an American social worker who spoke French to provide clinical supervision of CPT. Her job was to monitor PSAs' cases, check in regularly with PSAs and PSA supervisors, and liaise between them, Kaysen, and the AMHR study team in the US.

The VSLA intervention involved creating groups of 15–25 community members who voluntarily joined by purchasing "shares." Members could borrow money from the group's pooled savings and make monthly loan payments with interest. The group redistributed loan interest to its members annually according to their shareholdings; members used the funds to pay children's school tuition fees, rehabilitate homes, or buy livestock, for example. VSLA groups also provided a form of insurance called "social funds," from which members could withdraw funds interest-free in emergencies (e.g., house fires, family illness).⁴⁷

Participant Selection

AMHR and the IRC selected 14 villages in South Kivu and 2 villages in North Kivu for the study (see **Exhibit 11** for trial details). They grouped the villages into clusters of two to four based on proximity and shared language and randomly assigned them to provide either group-based CPT for up to 24 women or the IRC's existing individual psychosocial support and referral services for an unlimited number of women.

PSAs traveled to villages to explain the trial. "The Congolese staff were so dedicated—they did all the legwork," said Bass. In December 2010, the IRC worked with PSAs to recruit women for the intervention by reviewing case management files of current and prior clients; women over 18 who had experienced or witnessed sexual violence were eligible. The PSAs then invited candidates to an IRC listening center to learn more about the study and, if interested, consent to participate.

Consenting women completed intake questionnaires; those with a total symptom score of 55 and a functional-impairment score of at least 10 were eligible. The research team excluded seven women it identified as actively suicidal. The JHU social worker spoke with these women and identified a friend or family member who could commit to closely monitoring each and updating the JHU social worker until the suicidal thoughts resolved.

Training PSAs and PSA Supervisors

The IRC chose 14 women (some already PSAs) from its partner NGOs to complete CPT training with the PSA supervisors. PSAs had between one and nine years of experience providing case management and individual supportive counseling to survivors of sexual violence and at least four years of post-primary school education. They worked with an NGO in their village or a nearby village.

Working from the US, Kaysen spent a month adapting CPT training materials she had used in Northern Iraq for PSAs in the DRC. "The standard CPT manual is written by psychologists for psychologists, so there's a lot of theory, which is beautiful and elegant but doesn't help paraprofessionals deliver the treatment. We shortened it from 250 pages to 46 pages," Kaysen said. A Congolese interpreter spent 2–3 months translating the materials into French. "I had to make sure the vocabulary and expressions in the manual made sense to the PSAs and their supervisors," he said.

Kaysen extended the training course, which took place in early 2011, from the standard two days to two weeks to allow the interpreter to translate to French and local languages (e.g., Swahili, Mashi) as needed and to account for the limited training and experience of PSAs. The PSAs worked with the interpreter and supervisors to ensure they understood everything. "We had an amazing group of women," Kaysen said. Trainees' experience varied; some had been providing psychosocial support services for a few months, while others had been working with survivors of sexual violence for close to a decade.

PSAs learned through role-play—a standard pedagogical approach for training lay health workers—how to deliver a 12-session CPT treatment. The interpreter translated what trainees said for Kaysen, who provided feedback in English, which the interpreter translated into French. The PSAs also practiced the

initial one-hour meeting they would have with each participant to verify her symptoms, explain the purpose and structure of the intervention, describe the participation requirements, and discuss her availability. They confirmed that participants were comfortable with the group format of the program and, if they were, invited them to attend a second session, the first of 11 weekly meetings (see **Exhibit 12** for weekly session topics). Kaysen created measures for assessing knowledge uptake of PSA trainees.

The PSAs would be required to provide group-based CPT for their village on top of their regular psychosocial counseling and case management responsibilities. Kaysen recalled, "When the therapists looked at what it actually takes to learn CPT, some of them pushed back and asked, 'How can I continue seeing all of the women I'm seeing now and do this group?'" The study team trained and hired additional PSAs to share the workload, and Kaysen tried to increase their buy-in by asking for their ideas on how to encourage participant attendance and retention. One suggestion the IRC implemented was to schedule groups on market days as much as possible so that women could attend on their way to the market.

Kaysen also trained the PSA supervisors, who were chosen by the IRC. She emphasized the importance of praising the PSAs, some of whom were survivors of sexual violence themselves, to motivate them and build their confidence. Viviane Maroy—hired by the IRC as a technical officer for the GBV program in 2009—was the lead supervisor and directly supervised some of the CPT sites. The AMHR team trained her and other IRC staff to administer the study questionnaires to assess depression, anxiety, and PTSD symptoms (e.g., low energy, crying easily, recurrent nightmares) and functional impairment (e.g., difficulty performing tasks such as cooking and looking after children). The PSAs spent two months practicing their skills under supervision in a pilot phase. One PSA who was unable to perform was removed from the trial.

Implementation

The CPT and VSLA trials began in April 2011. CPT was implemented in seven villages, and individual support in eight. The IRC continued providing individual support in the villages in its catchment area that were not included in the study.

In each participating village, a PSA convened three different groups, each with a maximum of eight participants, for two hours weekly in either Mashi or Swahili. Most PSAs led their groups independently. In some groups, the supervisors co-led with PSAs initially so that the PSAs could learn from them. Supervisors had to travel long distances between sites; unsafe roads frequently prevented them from observing group sessions in the two furthest villages.

Supervisors noticed early on that some PSAs shied away from eliciting deeper responses from participants about difficult experiences and issues. "With more experience and support from their supervisors, the therapists eventually became more comfortable. The more you practice CPT, the more you perfect it," Maroy noted.

The IRC had a security team on the ground that briefed supervisors daily before they traveled to study sites. It was common for some sites to be deemed inaccessible for several weeks at a time. One staff member commented: "It's very fluid and highly unpredictable in the DRC. One month you have problems in one area, and the next month those problems move to another area. We provide support to sites through phone calls, but we can't always travel to them."

In case of emergency, each PSA had her supervisor's mobile phone number. Mobile phone connectivity was unreliable, however, and sometimes it took a few days to replenish credit—paid for by the IRC—on their phones, making it difficult at times for PSAs to contact their supervisors for help.

Supervisors evaluated the PSAs using a monitoring form and shared feedback directly after each session, including advice on how to engage participants who were disengaged or quiet. They might suggest a different technique or private conversation with the woman after group. They also helped PSAs use a preestablished protocol to identify and support participants at risk for suicide, homicide, or drug and alcohol abuse. Three IRC staff members each supervised a designated group of PSAs and supervisors. "CPT has a steep learning curve no matter where you are," Kaysen said, "so people need ongoing support."

The work was stressful for PSAs and their supervisors. "I was not prepared for the burnout," the social worker explained. "Some of the women's stories twist your ears emotionally—it's just unbelievable. There were many times when I would cry and could not sleep. And we were going at such a pace that there wasn't much time for self-care. I tried to keep everyone together and keep things moving." This sentiment was echoed by a PSA at the time: "We pass the day here, completing the tools [and] counseling others, and we don't have time to take care of our own families. I am starting to have problems at home." 52

Supervisors met with the AMHR social worker as a group every Monday at the IRC offices to submit their forms, symptom scores, and other data. They also discussed session highlights and challenges. A common observation was that many women reported they were "being heard for the first time," the social worker noted. "Participants believed they were alone in their experiences until they began CPT." Every week, the social worker Skyped with Kaysen for guidance and to debrief about the groups.

Security

More than 20 armed groups continued to operate in South Kivu. "We had never run a trial in a place where there was ongoing violence," Bass said. There was at least one major security incident in seven of the villages during the trial, including attacks by armed groups, murder, torture, kidnapping, looting, and displacement of CPT participants as a result. The IRC recorded each security incident to create a security score for each site and account for them in the RCT results (see Exhibit 13). In the weeks leading up to the general election in November 2011, the IRC temporarily suspended the program at all sites out of concern for the safety of IRC, research, and NGO staff.

A CPT participant was murdered after her group's seventh session (which focused on normalization), and lead PSA supervisor Maroy saw a flare-up in several women's symptoms. The IRC organized an emergency trip to discuss the event with the deceased member's group. "The women said they understood that it wasn't their or the woman's fault that she had been killed—rather, it was the fault of the insecurity in the country," Maroy recalled. She was impressed by their resiliency as they offered each other emotional support and prepared food for the woman's husband. The IRC offered one-on-one support to women who had more difficulty coping.

Faced with increasing turmoil throughout the region, IRC supervisors struggled to justify enforcement of the RCT's strict enrollment requirements. Congolese staff noted improvement in CPT participants' symptoms and wanted to make the intervention more widely available. One PSA explained, "We are doing CPT for survivors of sexual violence, but we could use it to treat survivors of all kinds of trauma. Direct victims of violence are not the only ones traumatized. I thank Johns Hopkins very much, but if the university could study how to use CPT for other survivors, that would be so important for the DRC."

Research Management

Coordination of the research alongside the IRC's regular GBV programming began to strain the organization's limited human resources and budget. An IRC team member explained, "The resources needed—the skills, time, and funding—were underestimated. Things ended up costing more than expected,

so we went through the budget more quickly than we intended and had to do more fundraising for supplemental grants. AMHR's money was dedicated to research costs, not programmatic costs. We had to give additional funding to our NGO partners to ensure they could do their regular activities properly and weren't impacted in a detrimental way by the CPT activities."

The IRC's GBV program adviser visited the DRC and sensed a disconnect between IRC field staff and the AMHR researchers, most of whom were US-based. "They didn't seem to understand when other aspects of our work interfered with the CPT," she said. "They would tell us that we were not committed to or prioritizing the research, to which I'd say, 'We are prioritizing it, but when we have a village that's just been attacked our priority remains helping survivors.' Sometimes it was difficult to explain that to them."

"Things happened and our team had to decide where we could be flexible and make adjustments, and where we had to be less flexible because of the research," Bass said. "Similarly, the IRC had to decide where they could and couldn't be flexible." As the programmatic partner on the ground, the IRC had final say in these decisions.

Staff involved in the RCT found it difficult at times to understand the roles of different players involved in the study and communicate effectively between them. "There were peaks and valleys," Annan said. "We started out strong because we had everyone around the table, but soon we realized we hadn't fully clarified who was doing and leading what, and there were assumptions made on different sides." Field staff typically needed approval from the provincial directors, who reported to the country director. The country director regularly consulted the Women's Protection and Empowerment Unit at headquarters.

In the midst of the CPT trial, the IRC hired a project manager to the Women's Protection and Empowerment team to oversee data collection, communication, and participant follow-up for the CPT and VSLA trials. By this time, most IRC staff involved in developing the project with AMHR had moved on. There was little overlap between outgoing and new staff, making it difficult to transfer knowledge. "The DRC is a tough place to get ex-pats to stay for a long period of time," Bass explained. "AMHR did not anticipate this and was frustrated when staff left and they lost momentum on the project," the VSLA program manager added. It was unclear whose responsibility it was to educate new IRC staff about the RCT and its importance; it was not a formal part of the IRC's onboarding process.

To improve coordination, the IRC and AMHR established a system of communication that included weekly calls about data collection and monthly calls for discussions of strategy, research findings, and challenges. Bass and Bolton, based in different US cities, discussed the RCT weekly.

Challenges continued during the follow-up period. AMHR found it difficult at times to work with the IRC field staff, many of whom were new hires and saw the study as "the Hopkins project."

Village Savings and Loan Associations

The IRC took the lead on designing the VSLA program. "This was their area of expertise," Bass said. The DRC VSLA manager was responsible for piloting and evaluating a small VSLA program with the goal of "developing and studying a larger program with AMHR," she said. She hired two VSLA officers to help set up and coordinate the program.

In October 2010, the IRC worked with CBOs to identify participants at nine study sites using selection criteria similar to the CPT trial: women age 18 or older who had experienced or witnessed sexual violence, exhibited at least some dysfunction and mental health symptoms through a baseline questionnaire, and were not actively suicidal.

The IRC invited eligible CPT participants who completed their therapy and other eligible women to an introductory meeting to obtain formal consent and inform them of the structure of VSLA groups. The women were then invited to attend a second meeting with 2–3 friends, regardless of their eligibility. At this meeting, the IRC encouraged women to form groups with other women they trusted and believed to be capable of saving money regularly. Groups of 15–25 applied to become a VSLA group. Of the 459 eligible women, 301 agreed to participate and joined one of the 66 VSLA groups included in the study. Half the groups were assigned to a waiting list and served as the control group.

The yearlong VSLA project began in April 2011. After three to four months of training in financial management skills (see **Exhibit 14** for a list of training session topics), the VSLA groups functioned independently.

The overlap between the CPT and VSLA studies was burdensome for IRC staff, who already were "overworked," Bass said. "Running complex trials concurrently put a lot of work on the field team. Though they were two distinct interventions, the research, coordination, and back-and-forth required for each was probably more than we should have taken on." A new hire noted, "I never knew whom I was supposed to copy on emails. There were so many parties involved, and while you want to keep everyone informed, you don't want to flood people's inboxes. It wasn't always clear who needed to sign off on different decisions."

The CPT trial concluded in July 2011. AMHR hired a doctoral student, Sarah Murray, to clean and enter the data, identify any issues (e.g., outliers, missing data), and analyze the data, first for the CPT trial and, later, the VSLA program.

When the VSLA pilot ended in March 2012, the IRC added 10 sites. The VSLA manager promoted the VSLA officers to supervisors and hired nine new employees—including a monitoring and evaluation officer—to support the program.

Results

Of the 405 women in the CPT study, 157 from seven villages received CPT, and 248 from eight villages received individual support. The IRC and AMHR collected one-month and six-month follow-up assessments. Six months after treatment, 77% completed the assessment, and only 9% of women who received CPT met the criteria for probable depression or anxiety, while 42% of women who received only individual counseling (the control group) met the criteria. The results were similar for PTSD.⁵⁰ One of the CPT participants described her experience: "Before, I felt ashamed and judged when I walked past others. I no longer feel ashamed. I feel at ease, and I can walk around without fear of being judged."

Only 57% of participants completed all three assessments (one baseline, two follow-up). Loss to follow-up was associated with older age, assignment to individual support, pregnancy at intake, and experience with or witnessing a wider range of traumas. Security problems also reduced the number of follow-up assessments.

The study team published its findings in the *New England Journal of Medicine* in June 2013.§ The study was the first scholarly impact assessment of psychological support to survivors of sexual violence in a conflict-affected country. "It was a well-designed study in a context where people sometimes feel like there's not a lot you can do," an expert in mental health in conflict settings said. "By publishing in NEJM,

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[§] Bass (AMHR) was first author, followed by Annan (IRC), Sarah Murray (AMHR), Kaysen and Griffiths (University of Washington), the IRC's DRC country director, Wachter (IRC), Laura Murray (AMHR), and Bolton (AMHR), identified as the senior author.

they were able to reach a broad audience." AMHR paid the journal to translate the complete article into French so that the authors could distribute it within the DRC and other French-speaking African countries.

The IRC and AMHR believed the trial demonstrated that CPT could be implemented effectively by trained nonclinicians despite participant illiteracy and ongoing conflict. The IRC hoped to expand CPT to more women affected by sexual violence but would need new funding to continue the program.

To the research team's surprise and IRC staff's disappointment, the VSLA study results were mixed. Participants reported less hunger ("higher food consumption"), experienced less stigma, and had slightly better financial outcomes than control group members. On average, VSLA members saved USD 36.35 and earned a return on investment of USD 51.95 over one 9–12 month cycle, for an average profit of 42.4%.⁵³ The impact on mental health outcomes was less compelling. Symptoms of depression, anxiety, and trauma improved for many women in both the VSLA and control groups, and around 40% of women still experienced high depression and anxiety symptoms at the end of the program.⁵³

Sarah Murray believed the null effects on mental health may have been due to the participants' high degree of stress. "Group participation in a brief microfinance intervention may not reasonably be able to address severe distress," she said. "Or, it could be that we needed to assess mental health impact over a longer time period." The IRC and AMHR teams decided to continue offering the VSLA program, which had become very popular among participants and staff, but stopped framing it as a mental health intervention, focusing instead on its economic and social benefits.

Following the study, the IRC conducted an internal retrospective cost-effectiveness analysis to inform future planning. It estimated the indirect and direct programmatic costs of the CPT trial to be USD 240,214.38 for 157 total beneficiaries (USD 1,530.03 per beneficiary). For the VSLA, the indirect and direct costs totaled USD 592,598.88 for 833 total beneficiaries (USD 711.40 per beneficiary).** When looking at the cost of other VSLA implementations that did not include RCTs, the IRC estimated the RCT accounted for 50–60% of the total VSLA costs in the DRC. VSLA and CPT costs were greatest at program inception.**

Dissemination

The IRC and AMHR organized meetings in Bukavu and Goma, the capital city of North Kivu, to share study results with staff and try to convince the government and other NGOs to adopt CPT. "Those who are traumatized by violence are never just traumatized—they have other health needs as well," a PSA supervisor noted. Meeting attendees included IRC staff, MoPH representatives, academics, and local and international organizations working in health, women's rights, GBV, and other related fields. An interpreter translated the meetings, conducted in English.

"The PSA who spoke about her experience with CPT made people appreciate that you don't have to have a PhD to practice CPT in the field," a Congolese IRC staff member observed. "Her presentation was moving and encouraging; people in the room were very inspired."

The MoPH was excited by the CPT results and immediately interested in collaborating with the IRC to pilot the intervention in select primary health care facilities in South and North Kivu.

Staff and community partners were astonished by how much money VSLA participants had saved and disappointed by the null effects on mental health. "We explained that this is what we know at this point," Sarah Murray said, "and it doesn't mean that it's not a useful program in other ways."

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^{**} In 2005, the average annual cost of first-line antiretroviral treatment for HIV in the DRC was USD 348 per patient. 54

^{††} The data in this paragraph are provided for educational purposes. They represent the best available data at the time the case was written. The IRC has not verified accuracy.

Looking Ahead

By 2013, the IRC was operating Women's Protection and Empowerment programs in 18 countries. In the DRC, its GBV and other programs employed over 900 people, 96% of whom were Congolese. Its USD 70 million DRC budget—largely funded by the UN and American and European agencies—covered GBV, emergency assistance (water, sanitation), development projects, education, and strengthening public primary health care.⁵⁵ The IRC expanded its popular VSLA program to nearby provinces in the DRC; other international NGOs began offering it as well.⁵⁶

David Miliband, former Secretary of State for Foreign and Commonwealth Affairs in the United Kingdom, became the IRC's president and chief executive officer in 2013. One of his priorities was to expand the limited evidence base for humanitarian interventions. "Government donors should establish a new principle of only funding programmes that are based on sound evidence, or which will generate that evidence," he wrote.⁵⁷ "The growing evidence about aid suffers from the same problem as aid itself: it focuses far too much on relatively stable countries, with fewer than 100 impact evaluations conducted in crisis-affected places."

The IRC created two Mental Health Technical Advisor roles to integrate mental health and psychosocial support into its health, protection, education, and US offerings programs.⁵⁸ In the DRC, the IRC received a grant from the Humanitarian Innovation Fund (USD 240,000) to help the MoPH train 21 government health care providers in CPT; they served 117 survivors of sexual violence in South Kivu.⁵⁹ The IRC lacked funding to continue the program beyond the one-year grant; however, Judy Bass and Debra Kaysen continued working with the MoPH and an international faith-based NGO to expand CPT to three health zones through a large USAID-funded GBV program in eastern DRC.^{56,60} Bass and colleagues followed up with CPT participants and PSAs in six villages from the original IRC trial in early 2017 and hoped to complete data analysis in November.

By 2017, the IRC had conducted 74 research projects—including 32 controlled trials—in 25 different countries, many of which were conflict settings.⁶¹ It developed web-based tools to help its staff and other humanitarian agencies make evidence-based decisions about programming.^{‡‡}

An expert in mental health and conflict settings described the significance of the IRC's CPT trial and how the global mental health field had evolved since its publication:

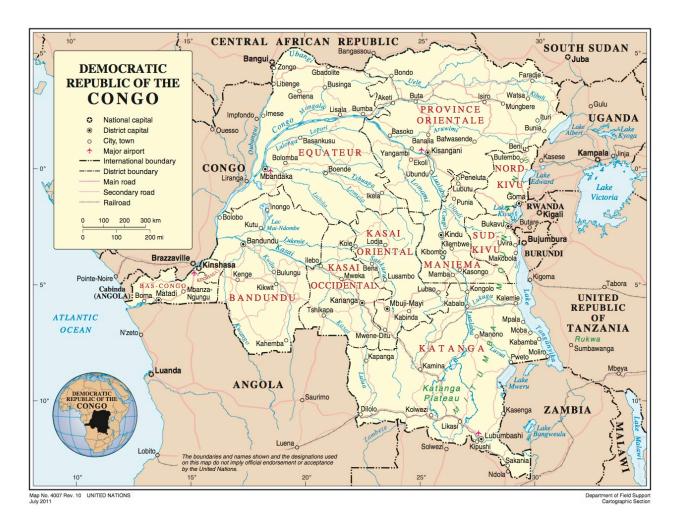
This trial was a key well-designed intervention study done in partnership with a major humanitarian organization that, with positive results, had the potential to take the intervention to scale. Millions and millions of dollars are being invested in humanitarian responses, but not enough attention is being paid to mental health or the effectiveness of mental health interventions in conflict-affected settings. The IRC's work is one important brick in the foundation for more evidence-based practice in the context of humanitarian emergencies.

Wachter reflected on the tremendous time and resources that had gone into the research. While she was proud of what the IRC and its partners had achieved in such a volatile setting, she wondered if the RCTs had been worth it, and for whom. How could the study findings contribute to improving services for vulnerable populations in the region and beyond?

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^{‡‡} https://www.rescue.org/report/cost-analysis-methodology-irc; http://oef.rescue.org/#/? k=t5zrea.

Exhibit 1 Map of the Democratic Republic of the Congo



Source: United Nations, via University Texas at Austin's Perry-Castañeda Library, http://www.lib.utexas.edu/maps/map_sites/country_sites.html#c.

Exhibit 2 Background on Global Mental Health

According to the World Health Organization (WHO), mental health is a "state of well-being in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community." ⁶² In 2013, there were more than 150 clinically diagnosable mental disorders, "characterized by clinically significant disturbance[s] in an individual's cognition, emotion regulation, or behavior that [reflect] a dysfunction in the psychological, biological, or developmental processes underlying mental functioning." ⁶³

Mental health disorders contributed 7.4% of disability-adjusted life years (DALYs)§§ worldwide in 2010 and cost LMICs USD 870 billion annually.64 Costs included increased utilization of social, educational, criminal justice, and other services for people with mental illness,65 as well as productivity losses owing to mental health-related disability, unemployment, and premature death.66 Mental health had been largely absent from the global health agenda.67,68 The Millennium Development Goals did not address it, and spending on mental health worldwide was less than USD 2 per person in 2011. In low-income countries, it was less than USD 0.25 per person annually.69 On average, countries in Sub-Saharan Africa spent less than 1% of their total health expenditure on mental health,70 compared with nearly 20% on HIV/AIDS.71

A variety of health and social service professionals could provide mental health care, depending on the severity of the issue, including psychiatrists, psychologists, social workers, counselors, and nurses. Psychiatric and non-psychiatric nurses provided most mental health care globally.⁶⁹ In 2005, the WHO estimated it would take an additional 1.71 million mental health workers to close the treatment gap in LMICs by 2015.⁷²

Treatments for mental disorders included psychotherapy, individual or group counseling, case management, support groups, hospitalization, and/or medication. Psychotherapeutic treatments—of which there were hundreds—used psychological methods to help patients resolve problems and develop healthier habits.⁷³ Validated approaches to psychotherapy included cognitive processing therapy (CPT), a standardized cognitive-behavioral treatment for PTSD and other trauma symptoms, and interpersonal psychotherapy (IPT), which focused on improving interpersonal functioning and social support for individuals experiencing psychological distress stemming from interpersonal issues.⁷⁴

According to a 2011 study, 98% of people with mental illness in developing countries never receive treatment. Barriers to delivering mental health care in such settings included lack of mental health funding,⁷⁰ limited mental health research in LMICs, a shortage of trained health workers,⁷⁵ and the stigma associated with mental illness.⁷⁵ Traditional healers, prayer groups, and family members were the primary sources of treatment for mental health problems in many countries, and facilities often treated patients in groups rather than individually to accommodate staffing constraints.^{25,66,72}

The Lancet published a Global Mental Health series in 2007 and 2011 to highlight gaps in mental health service delivery—particularly in LMICs—and develop a call to action.^{76,77}

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^{§§} The top 10 causes of DALY loss were cardiovascular and circulatory diseases (11.9%); diarrhea, lower respiratory infections, and other infectious diseases (11.4%); neonatal disorders (8.1%); cancer (7.6%); mental and substance use disorders (7.4%); musculoskeletal disorders (6.8%); HIV/AIDS and TB (5.3%); other non-communicable diseases (5.1%); diabetes, urogenital, blood, and endocrine diseases (4.9%); and unintentional injuries (4.8).

Exhibit 3 Definition and Key Features of Randomized Controlled Trials (RCTs)

Randomized controlled trials (RCTs) are hypothesis-driven, prospective studies that allow researchers to determine causation. Researchers view them as the gold standard in testing the efficacy of biomedical interventions. RCTs randomly assign trial participants to treatment groups or control groups. Treatment groups received the intervention(s) of interest, while control groups received standard-of-care. The goal of an RCT is to determine if any changes observed in the treatment group(s) were the result of the intervention as opposed to chance or other variables. RCTs are only considered ethical when there is genuine uncertainty within the biomedical community about the benefits of the treatment in question.

Clinical RCTs require considerable resources and operational capacity; therefore, a majority of them have taken place in high-income countries.

Source: Moher D, et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340. doi:http://dx.doi.org/10.1136/bmj.c869.

Exhibit 4 Frequency Table of Problems Identified by Informants Through Free List Interviews (n=34)

Problem Identified	Number of Respondents
	Who Mentioned the Problem
Hunger/malnutrition/lack of food	29
Theft/lootings (by soldiers/rebels)	25
Rape/sexual violence (by soldiers, in the fields, of young	20
children)	
Diseases	16
Lack of schools/destroyed schools/children with no education	14
Money: Lack of/looking for	12
Housing: Destroyed/lack of	11
Lack of farming/cultivating/fields not producing	11
Medicines/dispensaries: Lack of	9
Killings/murder	9
Jobs: Unemployment/lack of work	9
Lack of water/lack of drinking water	8
Lack of rain/drought	8
Fear: General/going to fields	8
Lack of energy/electricity	5
War	4
Fleeing/running away from the war	4
Death during war/people dying needlessly	4
Lack of clothes	4
Beatings in the home, by soldiers	4
Violence/military violence	3
Poverty	3
Food: Lack of/shortage	3
Eating badly	3
Abductions by soldiers/rebels	3
Sleeping (bad places, can't)	2
Loss of/lack of peace	2
Insecurity	2
Illiteracy	2
Hospital/health center: Lack of	2
Buildings: Uncomfortable or unable to build	2

Source: Murray L, Bass J, Bolton P. Qualitative study to identify indicators of psychosocial problems and functional impairment among residents of Sange District, South Kivu, Eastern DRC. 2006.

Exhibit 5 Functionality Tool

Functionality Tool Used to Assess Women

Prompt: How much difficulty do you have doing the task/activity compared with other women your age?

	Amount of difficulty doing the task/activity			tivity	
Tasks/Activities	None	Little	Moderate	A lot	Cannot do
Cultivate/farm					
Trade					
Cook					
Look after children					
Give advice for living peacefully					
Exchange ideas					
Domestic work					
Working—manual labor					
Pounding cassava					
Unite to do common tasks for					
community development					
Unite to do work for families					

Functionality Tool Used to Assess Men

Prompt: How much difficulty do you have doing the task/activity compared with other women your age?

	Amount of difficulty doing the task/activity				tivity
Tasks/Activities	None	Little	Moderate	A lot	Cannot do
Cultivate/farm					
Trade					
Breed					
Clothe and feed the family					
Unite and mutually provide pieces of					
advice					
Think of projects to help themselves					
Plan projects					
Plan for clothing and feeding the family					
Unite to work for the community					
Learn tasks for others to develop their					
lives					

Source: Murray L, Bass J, Bolton P. Qualitative study to identify indicators of psychosocial problems and functional impairment among residents of Sange District, South Kivu, Eastern DRC. 2006. Available at: http://pdf.usaid.gov/pdf_docs/PNADI610.pdf.

Exhibit 6 Men's and Women's Tasks by Functional Domain, as Perceived by a Small Sample of Rural Congolese Men and Women

Frequency Table of Tasks Respondents (n=21) Associated with Women

Tasks Related to Caring		Tasks Related to Caring		Tasks Related to Caring for	
for Oneself	for Oneself		for One's Family		
Task/Activity	#	Task/Activity	#	Task/Activity	#
Cultivating	15	Trading	19	Trading	7
Trading	15	Cultivating	12	Cultivating	6
Farming	6	Cooking	8	Farming	5
Trading/selling	4	Farming	8	Teaching	4
Studying	3	Selling	4	Breeding	2
Working in	3	Pounding cassava	3	Selling	2
association					
Church tasks	2	Working for others	3	Working with associations	2
Selling	2	Getting school fees	2	Working with others	2
Shopping	2	Teaching	2		
Manual labor	2	Working — generally	2		
		Brewing beer	2		

Note: "#" represents the number of respondents who mentioned a given task.

Table includes tasks named by one or more respondents.

Frequency Table of Tasks Respondents (n=13) Associated with Men

Tasks Related to Car	Tasks Related to Caring		Tasks Related to Caring		for
for One's Self		for One's Family		One's Community	
Task/Activity	#	Task/Activity	#	Task/Activity	#
Cultivating	8	Cultivating	7	Building	6
Breeding	6	Trading	7	Breeding	5
Farming	6	Farming	6	Cultivating	5
Trading	6	Healing	3	Farming	3
Teaching	5	Schooling children	3	Advising	2
Making beer	2	Teaching	2	Masonry	2
Making coal	2	Caring for children	2	Tailoring	2
		Getting clothes	2	Teaching	2
		Getting food	2		
		Looking for money	2		
		Making coal	2		
		Trading/selling	2		
		Transport (by bike)	2		

Note: "#" represents the number of respondents who mentioned a given task.

Table includes tasks named by one or more respondents.

Source: Murray L, Bass J, Bolton P. Qualitative study to identify indicators of psychosocial problems and functional impairment among residents of Sange District, South Kivu, Eastern DRC. 2006. Available at: http://pdf.usaid.gov/pdf_docs/PNADI610.pdf.

Exhibit 7 IRC Principles of Psychosocial Support and Case Management

Case management is a collaborative, multidisciplinary process that assesses, plans, implements, coordinates, monitors, and evaluates options and services to meet an individual's needs through communication and available resources to promote quality, effective outcomes. [...] Psychosocial support can be provided through the case management process. And by using a case management process, we can help survivors consider and manage the psychological and social consequences of the violence. For example, when a case manager provides emotional support to a survivor through words of understanding and support, helps survivors to learn about violence and its consequences, or helps survivors to cope with the social stigma attached to the violence by linking her with a support group—each of these seeks to improve a survivor's psychosocial wellbeing.

The principles that underpin case management are:

- Individualized service delivery based on the client's wishes
- Comprehensive assessment that is used to identify the client's needs
- Develop a service plan that meets a client's needs and is developed with her
- Good coordination of service delivery

Case Management Steps and Actions

Step	Action
Assess	• Get information: Why has the survivor come for help? What has happened? How does she see the situation? What needs does the survivor have? What supports does she have? Listen to the survivor's story, help her to identify her needs, and carefully and confidentially document information. Active listening is one of the most powerful elements of psychosocial care.
Plan	• What does the survivor want to happen next? To help a survivor plan how to meet those needs and solve problems, we give relevant information about available services. We help a survivor identify her options and help her make informed decisions about what she wants to do.
Implement the plan	• How can we help a survivor achieve her goals? This step means putting the plan into action and involves direct service delivery, referral for other services, advocacy on behalf of the survivor and supporting her through the process. The action plan is just a road map. When implementing a plan, consider a car with a driver and a navigator. The survivor has created a map and is driving the car, deciding how fast to go, where to turn, and when to stop. The caseworker is the navigator, helping the survivor maneuver through the steps in her plan or road map.
Follow-up and review	• This step includes following up to make sure the survivor is getting the help and services she needs to improve her situation and solve her problems. Is the situation better? Has the help been effective? It involves monitoring and evaluating the consequences for the survivor and identifying barriers to achieving outcomes. In your follow-up, you might identify additional needs and actions points and should therefore plan accordingly with the survivor. The plan of action should be time-framed and based on the survivor's needs.
Case	This usually happens when the client's needs are met and/or her own support systems are functioning.

Source: Adapted from IRC. 2011. *GBV Emergency Response & Preparedness: Participant Handbook*, pgs. 70-77. Available at http://cpwg.net/wp-content/uploads/sites/2/2013/08/IRC-2011-GBV_ERP_Participant_Handbook_-_REVISED.pdf.

Exhibit 8 IRC Budget Allocations, 2006–2008 and 2008–2009

Resource	2006–2008	2008–2009
Personnel	18%	30%
Capacity	4% (mainly psychosocial and	15% (43% psychosocial, 26% medical, 15%
building	community education)	community education, 15% institutional capacity
		building)
Advocacy	3%	10%
Direct	75%	45%
support/	• 35% CBOs, psychosocial	• 8% CBOs
funding to	and legal	• 30% psychosocial
partners	 40% fistula repair, funded 	• 7% legal
	by USAID-Safe	• 0% medical
	Motherhood, money	
	channeled to Panzi and	Note: Only capacity-building trainings are
	Health Africa by the IRC-	provided by IRC-GBV. All drugs and equipment
	GBV program. This	are provided by IRC Health or other medical
	component ended in April	INGOs. IRC-GBV covers the cost of survivors'
	2008 and is now managed	medical care where services are not free. This
	by USAID's partner,	money is included in the subgrant amount
	Engender Health.	awarded to psychosocial partners and is relatively
		minimal when compared with the entire budget.

Source: Bolton P & Locket D. (2009) Victims of Torture Fund Evaluation of the IRC Gender-Based Violence Program in the Democratic Republic of the Congo. USAID Report:http://pdf.usaid.gov/pdf_docs/PDACN138.pdf.

Exhibit 9 *CPT and VSLA Study Objectives*

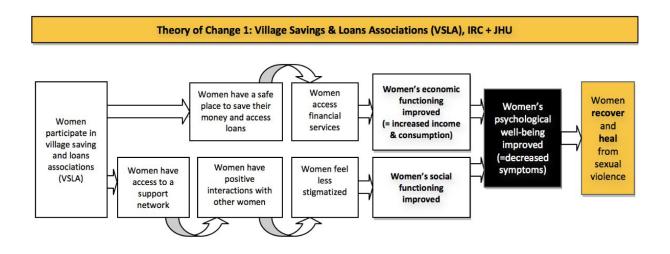
Specific Aim 1: To investigate the impact of a mental health intervention, cognitive processing therapy (CPT), on specific domains of social, physical, and economic functioning, and on the reduction of mental health problems, including depression, anxiety, and feelings of stigma and shame, associated with being an SV survivor.

Specific Aim 2: To investigate the impact of a socioeconomic intervention, Village Savings and Loans Associations (VSLA), on specific domains of social, physical and economic functioning, and on the reduction of mental health problems, including depression, anxiety, and feelings of stigma and shame, associated with being an SV survivor.

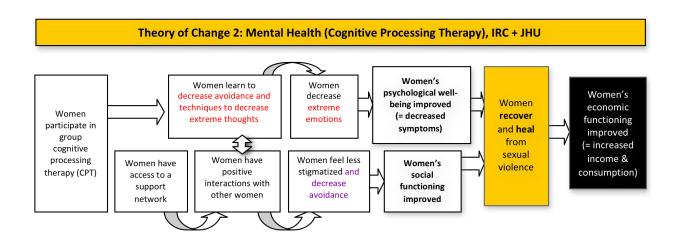
Specific Aim 3: To investigate the combined impact of a mental health intervention (CPT) followed by a socioeconomic program (VSLA) on specific domains of social, physical and economic functioning, and on the reduction of mental health problems, including depression, anxiety, and feelings of stigma and shame, associated with being an SV survivor.

Source: Bass, J., Bolton, P., Cetinoglu, T., Guilmond, MF, Wachter, K., Robinette, K., Annan, J. (2012). Addressing sexual violence related trauma in Eastern DRC with cognitive processing therapy.

Exhibit 10 Theories of Change for VSLA and CPT



Source: Study of Effectiveness of a Social-Economic Intervention for Sexual Violence Survivors in Eastern DRC, November 2014.



Source: Group Cognitive Processing Therapy: A Specialized Mental Health Intervention that Supports Improvements in Well-being for Sexual Violence Survivors. Johns Hopkins Bloomberg School of Public Health, International Rescue Committee.

Exhibit 11 Description of Cognitive Processing Therapy RCT

Using a mixed-methods approach, we selected, adapted, and tested measures. We conducted qualitative studies in three linguistically different communities to identify salient mental health problems of sexual violence survivors. Abandonment and rejection by family and friends, concerns about providing for self and family, fear, and stigma were major issues. Informants described psychological symptoms that were consistent with depression, anxiety, and PTSD. On the basis of these findings, they used the Hopkins Symptom Checklist (HSCL-25) to assess depression and anxiety, and the PTSD Checklist—Civilian Version to assess PTSD symptoms (both had been used internationally with sexual violence survivors and in conflict-affected settings). The checklists were adapted and pilot-tested in each language group. Assessment of functional impairment was based on the degree of difficulty in performing important tasks of daily living that were identified on the basis of qualitative data from the study villages. For each of 20 tasks, participants were asked to rate the degree of difficulty in performing the task. Women who had experienced or witnessed sexual violence were eligible for the study if they had a total symptom score of at least 55 and a functional-impairment score of at least 10. Suicidality that was judged by clinical staff to require immediate treatment was a criterion for exclusion. Study measures were translated into five local languages: Kibembe, Kifuliro, Kihavu, Mashi, and Swahili.

Results: A total of 65% of participants in the therapy group and 52% of participants in the individual support group completed all three assessments. Mean scores for combined depression and anxiety improved in the individual support group, but improvements were significantly greater in the therapy group. Similar patterns were observed for PTSD and functional impairment. At six months after treatment, 9% of participants in the therapy group and 42% of participants in the individual support group met criteria for probable depression or anxiety, with similar results for PTSD.

Source: Bass JK, Annan J, McIvor Murray S, et al. Controlled trial of psychotherapy for Congolese survivors of sexual violence. N Engl J Med. 2013;368(23):2182-2191. doi:10.1056/NEJMoa1211853.

Exhibit 12 Progression of Cognitive Processing Therapy Sessions

CPT Session	Activities
Session 1	Introduction to therapy (individual meetings): Verify symptoms, ask about
	availability, explain the therapy and how it will help them heal, explain the
	requirements of CPT, explain that the therapy is group therapy, and ask if they're
	still on board
Session 2	Introduction to cognitive processing therapy (first group session): Therapist
	explains the group interactions and dynamics, the goals and guiding principles of
	the group, women share their experiences (what happened to them)
Session 3	Meaning of the Event ("ABC")
Session 4	Identification of Thoughts and Feelings
Session 5	Identification of Stuck Points (maladaptive beliefs): How to be aware of and reflect
	on your thoughts, 5 questions of reflection
Session 6	Challenging Questions
Session 7	Challenging Beliefs
Sessions 8-12	Cognitive Modules: Safety, Trust, Power/Control, Esteem, Intimacy

Source: Bass, J., Bolton, P., Cetinoglu, T., Guilmond, MF, Wachter, K., Robinette, K., Annan, J. (2012). Addressing sexual violence related trauma in Eastern DRC with Cognitive Processing Therapy.

Exhibit 13 Security Incidents Across Sites

Site name	Incidents	Insecurity rating
Mabingu	Over 40 people kidnapped and taken into the forest. A young girl attacked and injured. One woman from group murdered.	High
Mantu	One attack on village. One person murdered. People fled to the forest for safety.	High
Lushebere	Bullets fired in the center of town by military. One soldier injured.	Low
Nyamakubi	Bullets fired in the center of town by military. One soldier injured.	Low
Kiliba	Two outbursts of fighting causing displacement. One house attacked, torture of inhabitants. One truck attacked, 2 military and 1 civilian killed.	High
Luvungi	Bandits attacked and robbed a convent and a health center, and killed two shepherds.	Low
Bishange	Attack and pillage of the parish and clinic.	Low

Source: IRC.

Exhibit 14 VSLA and Financial Literacy Training Sessions

VSLA	Activities
Session	
Session 1	Introduction to VSLA and election of group leadership
Session 2	Policies regarding share purchase, savings, loans, and the solidarity fund
Session 3	Development of VSLA ground rules/group constitution
Session 4	How to organize a savings meeting and record money saved
Session 5	How to count the money left in the fund and how to give credits
Session 6	How to share out funds at the end of the cycle

Financial	Activities
Literacy	
Session	
Session 1	Introduction to business
Session 2	Your business and you
Session 3	Increasing value
Session 4	Business planning
Session 5	Market information
Session 6	Marketing
Session 7	Cost calculation
Session 8	Pricing
Session 9	Archiving
Session 10	Financial planning

Source: Urwaruka Rushasha (New Generation): A Randomized Impact Evaluation of Village Savings and Loans Associations and Family-Based Interventions in Burundi.

Appendix Common Acronyms and Abbreviations

AMHR Applied Mental Health Research Group

CBO Community-based organization
CPT Cognitive processing therapy
DRC Democratic Republic of Congo
DALYs Disability-adjusted life years
GBV Gender-based violence
GDP Gross Domestic Product

IRC International Rescue CommitteeIPT Interpersonal psychotherapyLMIC Low- and middle-income counties

MoPH Ministry of Public Health

NGO Nongovernmental organization

PSA Psychosocial Assistant

PTSD Post-traumatic stress disorder RCT Randomized controlled trial

REL Research, Evaluation, and Learning Unit

STI Sexually transmitted infection

UN United Nations

UNHCR UN High Commissioner for Refugees
USAID US Agency for International Development
VSLA Village Savings and Loan Association

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