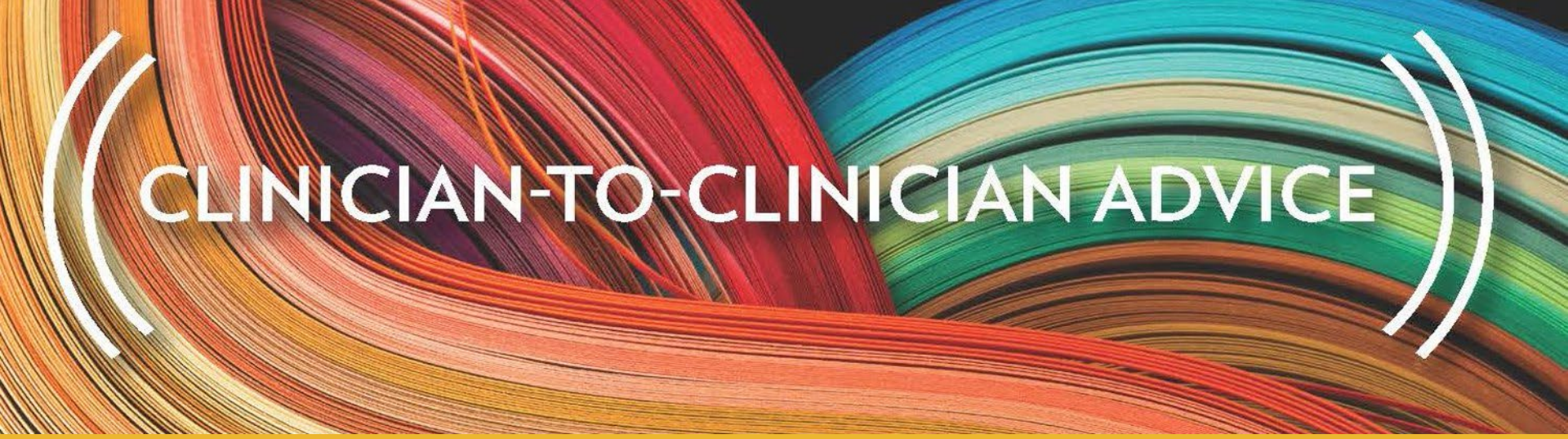

How Much DAA Treatment is Enough? Outcomes From a Large Case Series of HCV Treatment Interruptions

Astha Kanani, MD; Christopher Bositis, MD, AAHIVS; Carolyn Chu, MD, AAHIVS; Sean Brennan

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Authors

Astha Kanani, MD

Clinician Consultant, NCCC

Chris Bositis, MD, AAHIVS

Clinical Director, NCCC
Clinical Associate Professor of Family and Community Medicine

Carolyn Chu, MD, MSc FAAFP, AAHIVS

Principal Investigator, NCCC
Professor of Clinical Family Community Medicine

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Background and Objectives

- Simplified therapy with direct-acting antivirals (DAAs) has greatly expanded low-barrier hepatitis C virus (HCV) care including primary care-based treatment.
- Despite short treatment duration, treatment interruptions are common and there is a paucity of data to guide clinical management.[1,2,3,4]
- The National Clinician Consultation Center (NCCC) reviewed cases of HCV treatment interruption received on its national Hepatitis C Warmline and describes clinical outcomes after treatment interruption.

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Methods

- The NCCC is a federally funded education and capacity-building resource that provides free, telephone-based consultation to any U.S. healthcare provider seeking guidance on HCV prevention, diagnosis, and treatment.

- Deidentified case information is provided by callers and documented within the NCCC's secure consultation database, along with consultant recommendations.

- Calls involving HCV treatment interruptions received between September 1, 2022, to August 31, 2023, were retrospectively identified and reviewed for clinical information including genotype, fibrosis score, prior DAA treatment experience, number/timing of missed doses, DAA interruption management, care setting, NCCC consultant recommendations, and SVR12 outcomes.

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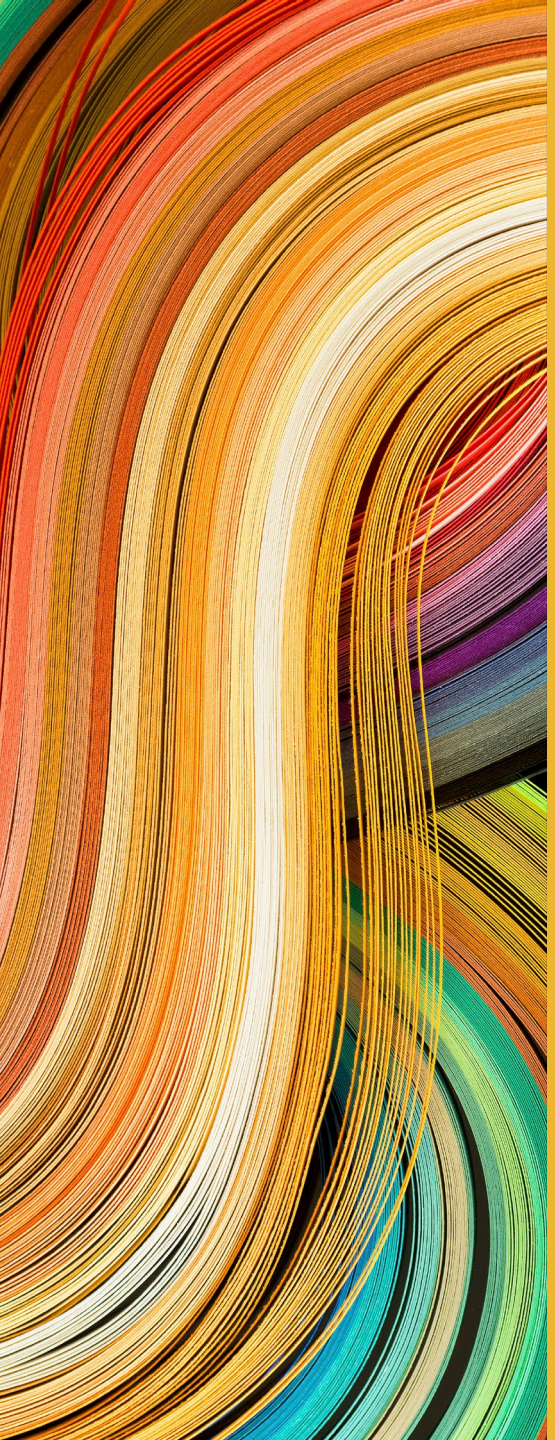

How Much DAA Treatment is Enough? Outcomes From a Large Case Series of HCV Treatment Interruptions

Results

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Results

- During the review period, 61 out of 541 calls (11%) to NCCC's Hepatitis C Warmline involved cases of DAA treatment interruption.
- Patient age ranged from 20-76 with a median age of 47.
- 82% of the calls were from an outpatient community-based care setting and 11% were from providers serving patients/communities in Indian Country.

Results

In this case series of 61 patients with HCV treatment interruption from mostly primary care health settings, of available outcome data, we found that SVR rates were high (90%) despite a wide range of missed doses of DAA therapy.

23/32 patients: had no SVR data due to patient being lost to follow up

9/32 patients: NCCC unable to reach provider to confirm follow-up information

Reasons for patient loss to follow-up

- Incarceration
- Pharmacy delivery issues
- Side effects
- Unstable housing
- Unstable mental health
- Substance use

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Results

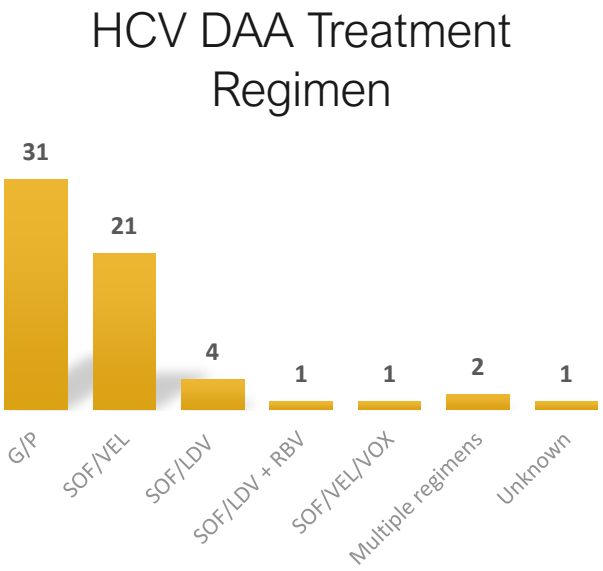

Fig. 1

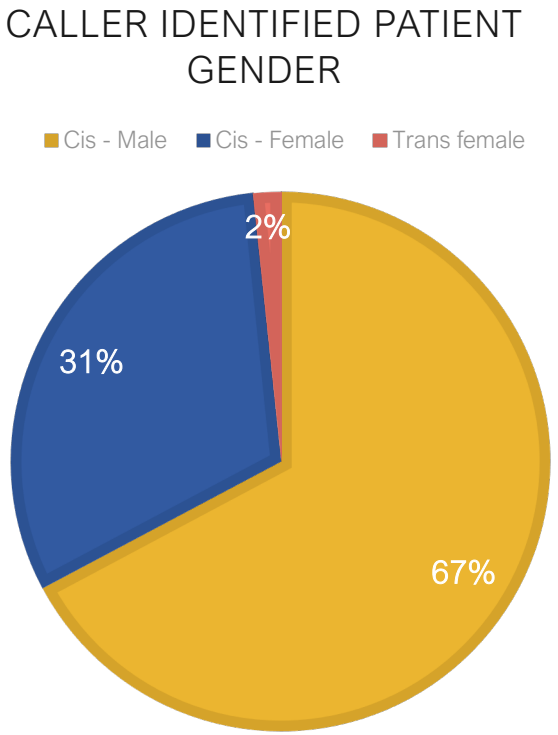

Fig. 2

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Results

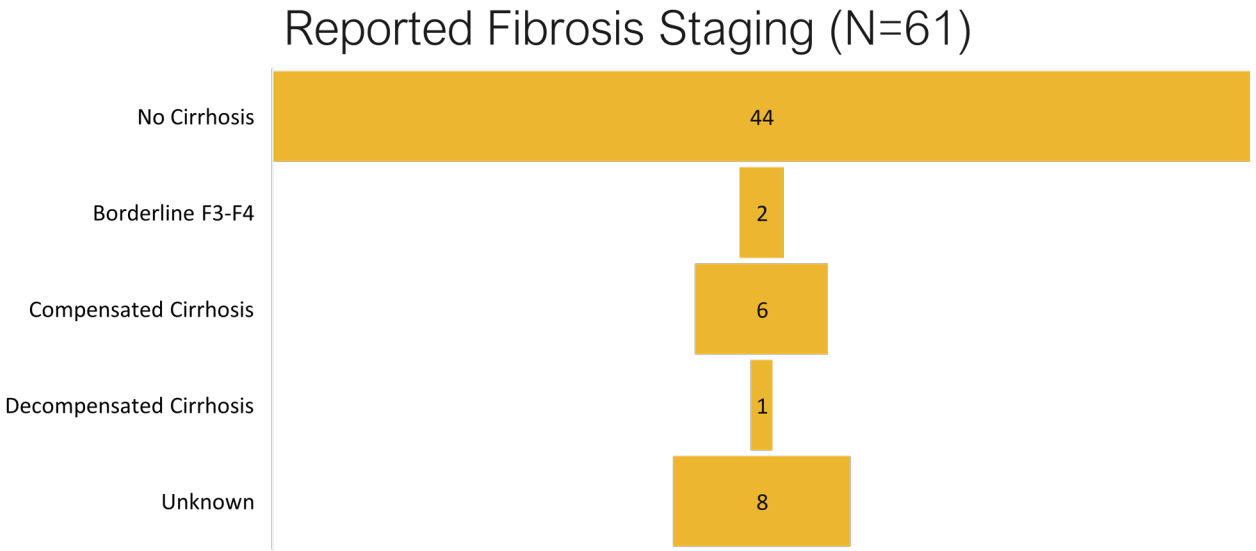

Fig. 3

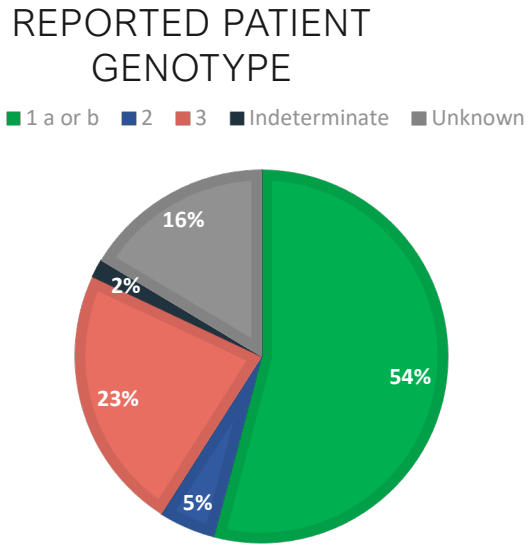

Fig. 4

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Results

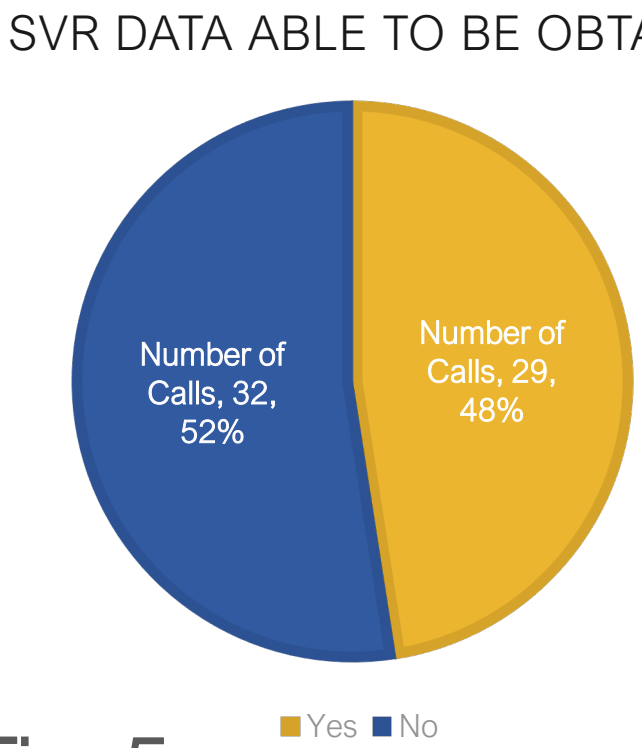

Fig. 5

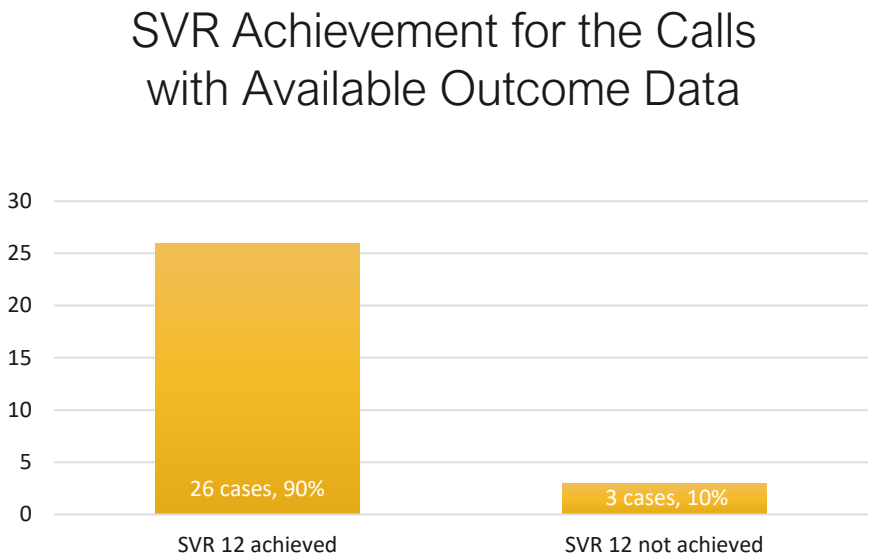

Fig. 6

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Table 1: Characteristics of patients with one round of DAA treatment with SVR data

Characteristics	Treatment naïve, SVR12 available (n= 21)	Timing of Treatment Interruption	
		Day 1-28 (n=3)	After Day 28 (n=18)
Genotype			
1	11	3	8
2	1	0	1
3	4	0	4
Other/unknown	5	0	5
Fibrosis score			
F1-F3	17	3	14
F4	2	0	2
Unknown	2	0	2
DAA regimen			
G/P	15	2	13
SOF/VEL	4	1	3
Other	2	0	2
% doses missed*			
Median	31%	25%	37.5%
Range	9-67%	12-30%	9-67%
Achieved SVR12	19/21 (93%)	3/3 (100%)	16/18 (89%)

*When known. Late = missed dose

Table 2: Characteristics of patients with multiple rounds of DAA treatment with SVR data

Patient Age/Gender	Genotype	Fibrosis Staging	DAA Treatment Description	% Missed Doses	Treatment Interruption reasons	SVR Achieved?
54 trans-female	1a	F1	• 1st round - G/P in 7/2022 • 2nd round - SOF/VEL in 3/2023*	• 81% missed first round • Had some gaps, unknown quantity	• Relapse w/ meth use • Mental health struggle	Yes
36 cis-male	1a	No cirrhosis	• 1st round - SOF/VEL in 4/2021 • 2nd round - G/P 3/22*	• 58% missed first round • 12.5% missed 2nd round	• Relapse w/ meth use • Relapse w/ opioid use	Yes
52 cis-male	1a	F4	• 1st round - G/P in 2019 • 2nd round - SOF/VEL/VOX in 2/2023	• 50% missed first round • Unknown missed 2nd round	• Alcohol use	Yes
37 cis-male	1a	F4	• 1st round - G/P in 2020 • 2nd round - SOF/VEL in 11/2022*	• 87.5% missed first round • 15.4% missed 2nd round	• Unknown • Incarceration	Yes
48 cis-female	3	F0	• 1st round - SOF/VEL in 2021 • 2nd round - SOF/VEL/VOX in 9/2022	• 66% missed first round • Unknown missed 2nd round	• Alcohol use/GI said stop taking due to Alcohol	Yes
31 cis-male	1a	F0/F1	• 1st round - SOF/VEL in 7/2021 • 2nd round - SOF/VEL/VOX in 3/2022*	• 66% missed first round • 66% missed second round	• Relapse w/ meth use • Relapse w/ opioid use • Unhoused	Yes
54 cis-male	1a	F3	• 1st round - Unknown DAA 2010 • 2nd round - G/P in 2018 • 3rd round – G/P 2/2023*	• Unknown missed first round • 75% missed second round • 0% missed third round	• Traveling for job • Alcohol use	Yes
48 cis-male	3	No cirrhosis	• First round – SOF/VEL in 2022 – took 4 weeks • Second round – SOF/VEL in 6/2023*	• 66% missed first round • Unknown % - provider thinks completed 12 weeks	• Stomach upset • None reported	No

* Did not match with treatment interruption recommendations published by American Association for the Study of Liver Diseases at that time.

Conclusions

- This series of over 60 HCV treatment interruption cases provides additional "real world" data including SVR12 outcomes.
- Despite a wide range of missed doses, with many cases treated through primary care clinics and other low-barrier settings, 90% with available follow-up data achieved cure.
- Of eight cases undergoing retreatment, 88% were able to achieve SVR. First line DAA's were "recycled" in 5/8 of these patients.
- Of 32 patients with missing follow-up information regarding SVR12 outcomes, the majority (72%) was due to patient loss to follow-up—this highlights the importance of early identification of those at risk for, and interventions to prevent, loss to follow-up.
- For cases with available follow-up and SVR12 information, our results affirm SVR12 occurs even with "imperfect" DAA adherence
- Limitations of our study: information relied on provider review and recall, which may have impacted data accuracy and completeness
- More research on the role of "recycling" first-line DAAs is needed, as well as additional information on optimal management of HCV treatment interruptions

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1) Fabbiani M, Lombardi A, Colaneri M, et al. High rates of sustained virological response despite premature discontinuation of directly acting antivirals in HCV-infected patients treated in a real-life setting. J Viral Hepat. 2021;28(3):558-568.

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3) Rosenthal ES, Silk R, Mathur P, Gross C, Eyasu R, Nussdorf L, Hill K, Brokus C, D'Amore A, Sidique N, Bijole P, Jones M, Kier R, McCullough D, Sternberg D, Stafford K, Sun J, Masur H, Kottilil S, Kattakuzhy S. Concurrent Initiation of Hepatitis C and Opioid Use Disorder Treatment in People Who Inject Drugs. Clin Infect Dis. 2020 Oct 23;71(7):1715-1722. doi: 10.1093/cid/ciaa105. PMID: 32009165; PMCID: PMC7755091.

4) https://www.hcvguidelines.org/evaluate/monitoring#incomplete-adherence

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HIV/AIDS Warmline **800-933-3413**	HIV treatment, ARV management, complications, and co-morbidities
Perinatal HIV Hotline **888-448-8765**	Pregnancy, infant feeding and HIV
Hepatitis C Warmline **844-HEP-INFO/** **844-437-4636**	HCV testing, staging, monitoring, treatment
Substance Use Warmline **855-300-3595**	Substance use evaluation and management
PrEPline **855-HIV-PrEP**	HIV pre-exposure prophylaxis
PEPline **888-448-4911**	Occupational & non-occupational exposure management

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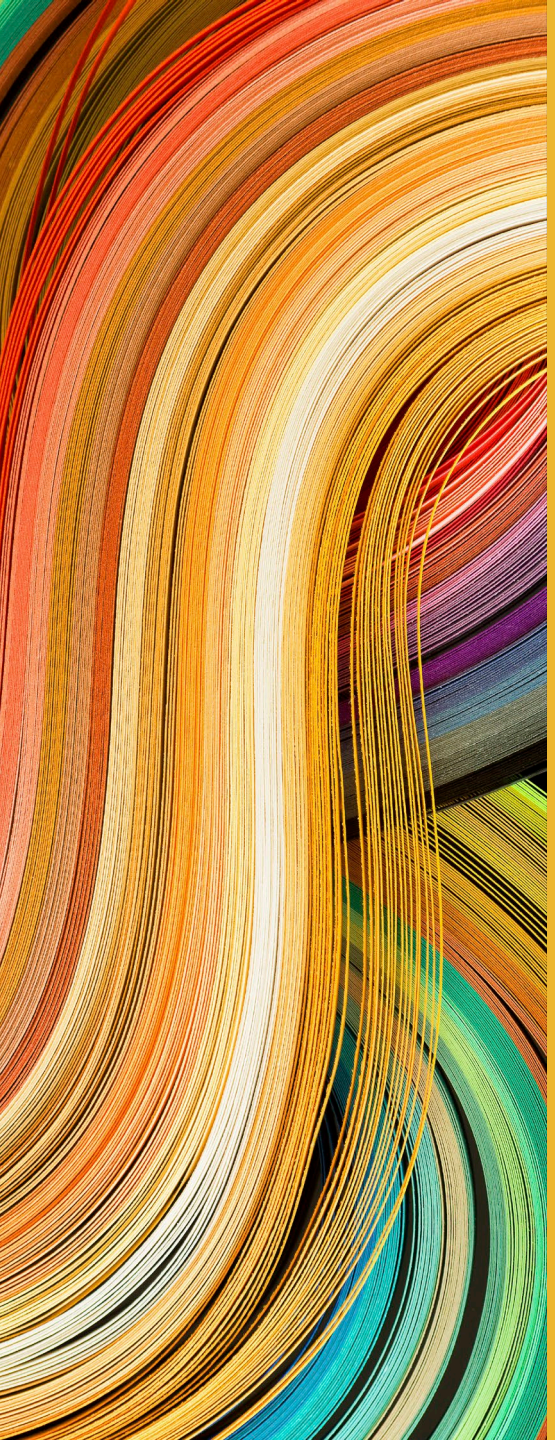

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