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ORIGINAL ARTICLE

Evaluating and communicating hepatitis C cascades of care data in Tayside, Scotland: A journey towards elimination

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Abstract

Chronic hepatitis C virus (HCV) is one of the leading causes of liver cirrhosis and hepatocellular carcinoma. The WHO 2030 Elimination Goals require each country to evaluate their response to their epidemics. This can be achieved by visualization of cascades of care, depicting how infected cases move through disease control stages. However, methods of displaying data are debated and lack practical application. This project proposes a new way of codifying and displaying HCV data using Tayside as a case study. 1464 cases of active HCV infections in Tayside from 2015 to 2019 were analysed from NHS Tayside's HCV Database. Variables were evaluated to create a systematic coding framework that was then used to code each patient's diagnosis, treatment and cure status each year from 2015 to 2019. Graphical representation of the data in the form of a stacked clustered bar chart demonstrates general trends and conversion rates. For example, Tayside has seen an increase in diagnosis-to-cure rates from 18% to 49% (2015-2019). This method also demonstrates the portion of newly and previously diagnosed people accessing treatment, those with unsuccessful or incomplete treatments, completed treatments with unconfirmed cure, and the number of deaths and relocations. In conclusion, this project proposes a novel way of displaying cascades of care data that relays yearly snapshots of an epidemic, cumulative progression over time, nuanced information of each stage and progression towards elimination targets. This method can be meaningfully used to improve local service planning, knowledge exchange across health systems and reporting to bodies like the WHO.

KEYWORDS
communicable diseases, epidemiology, hepatitis, hepatitis C, public health

1 | INTRODUCTION

Chronic hepatitis C virus (HCV) is one of the world's leading causes of liver cirrhosis and hepatocellular carcinoma with wider health impacts like cardiovascular disease, mental health issues and renal complications.[1,2] HCV is a blood-borne virus that impacts around 71 million people globally and approximately 34,500 people in Scotland where it is transmitted most commonly through injection drug use.[1,2]

While there is some emerging evidence that antibodies may be partially protective,[3] there is no vaccine available, making prevention

Abbreviations: CoC, Cascade of care; DAAs, Direct acting antivirals; DBST, Dry blood spot test; HCV, Hepatitis C virus; HMP, Her Majesty's Prison; ICE, Integrated Clinical Environment; PCR, Polymerase chain reaction; SVR, Sustained virologic response; WHO, World Health Organization.

TABLE 1 inclusion and exclusion criteria

Inclusion Criteria:	Exclusion Criteria:
a. Any patient alive at any point from 1st January 2015 – 31st December 2019 AND b. In Tayside for longer than 2 months (including those in custody of Tayside HMP) AND c. With at least one HCV infection (PCR positive, DBST positive or antibody positive with no subsequent negative PCR) Any patient diagnosed and treated before 2015 without a successful SVR, that was alive in Tayside between 2015 and 2019 Any patient in Tayside treated with DAAs starting in 2014 and ending in 2015	a. Any patient treated and cured prior to 1st January 2015 b. Any patient that died before 2015 c. Any patient that spontaneous resolved before 2015 (Antibody positive, PCR Negative) d. Any patient in Tayside for less than 2 months e. Tayside residents who moved away from Tayside before 2015 and did not return f. Tayside residents still in custody of HMP outside of Tayside

difficult and reinfections common in high-risk populations. The variable diagnosis-to-cure journeys, transient populations and possibility of reinfection present challenges to health services attempting to monitor and visualize the progression of their epidemic or the efficacy of pathways.

HCV was once treated with interferon-based regimens, which were lengthy and posed significant side effects, mediocre cure rates and poor compliance.[2] Between 2013 and 2015, direct acting antivirals (DAAs) became the standard of care for many countries like Scotland, providing an easily administered oral option with over 95% efficacy across genotypes.[4] With the introduction of DAAs, eradication of the disease has become possible and the World Health Organization (WHO) has set Elimination Goals for 2030 tasking each health system with evaluating their own epidemic and progress towards said targets. These include a 90% diagnosis rate, 80% treatment rate of those eligible, 90% reduction in incidence and 65% reduction in mortality.[5] The WHO has highlighted priority actions for countries such as information gathering, prevention, national target setting and revising plans as necessary.[6]

In order to monitor both the progression of an epidemic towards targets and utilize the metrics to make strategic healthcare provision decisions on the ground, data must be collected and communicated effectively. Insights about an infectious disease epidemic, like that of HCV, can be gained by analysing a health system's cascade of care (CoC) which depicts how infected cases move through the steps of effective disease control in a continuum of services.[7] CoC has been effectively used to identify gaps in HCV care, plan service delivery to intensify efforts in key areas, evaluate the progression of the epidemic and monitor health system effectiveness in order to improve the health and increase the treatment rates of those living with HCV.[8-11]

While CoC is used around the globe, approaches to data coding, analysis and reporting vary.[12] Hepatitis C specialist teams have debated the best ways to capture yearly snapshots of the current state of the epidemic, appreciate how the epidemic changes over time, emphasize the nuances at each stage of the cascade and compare how progress meets set targets. A standardized method would facilitate the comparison and knowledge exchange across time, settings, subpopulations and health systems.[6]

In order to evaluate yearly snapshots of an epidemic, its cumulative evolution over time, nuance at each stage of the cascade and progression towards elimination targets, this paper proposes a novel, systematic way of codifying HCV cases along the proposed cascade of Care: Diagnosis, Treatment and Cure. It also evaluates the hepatitis C cascade of Care in Tayside, Scotland, to provide examples of insights gained from displaying data in this way.

2 | METHODOLOGY

2.1 | Data sources

NHS Tayside maintains records of all patients who have tested positive for hepatitis C RNA or antibodies since 1993, including those who are only temporarily in the region, those who spontaneously resolve the infection and have undetectable HCV RNA levels and those who have relocated from the region either temporarily or indefinitely. The current database holds demographic and clinical information of 3917 people over 18 years old.

In order to capture each patient's HCV timeline, variables including PCR positive test dates, past medical history, DAA treatment start dates and statuses, cure dates, death dates and relocation history were collated from the local HCV database, NHS Tayside Clinical portal and Sunquest Integrated Clinical Environment (ICE) system, which reports patients' laboratory results. Qualitative information regarding treatment status and relocation history was gathered from clinical letters recorded from the pharmacy service, harm-reduction service, Tayside Substance Misuse Service, and other health or social care services, where available. Caldicott Guardian approval was obtained to access patient data (ref: IGTCAL4762).

2.2 | Cohort selection

A cohort of individuals with active infections after the widespread introduction of DAAs in 2015 was identified. The inclusion and exclusion criteria are outlined in Table 1. For clarity, those that began treatment with DAAs in late 2014 and finished in 2015 were included as they were the early adopters of what would become standard care in 2015 (n = 9). Also, those treated with interferon after 2015 were included as they were part of a clinical trial and contributed to Tayside's overall epidemic (n = 70); any subsequent infections and treatments with DAAs in these individuals were coded as usual. All HCV positive people that were prisoners for at least two months in Her Majesty's Prison (HMP) in Perth were included as they fall under Tayside's medical service provision, contribute to Tayside's prevalence and potentially transmit to other Tayside residents for the duration of their stay. Those that moved in and out of Tayside more than two times over the five years were not considered residents in Tayside and were, therefore, excluded from the

analysis. All people that had been treated before 2015 and had not had confirmed SVRs and people with a positive antibody test but no subsequent PCR data have been included as they may still have active infections. Reinfections in the same person, whether in the same year or in subsequent years, are coded as separate infections, treatments and cures.

Figure 1 outlines the cohort selection process based on inclusion/exclusion criteria. 1476 people that were alive, in Tayside, and had at least one active hepatitis C infection since 2015 were ultimately included in the study cohort.

2.3 | Coding framework

Using the variables to identify important statuses in the diagnosis-to-cure journey, a framework was created to codify each patient's Diagnosis, Treatment and Cure status at each point in time (Table 2). The coding framework was then used to codify each of the 1476 patients in our data set each year from 2015 to 2019 to produce an example stacked clustered bar chart. Details of the methodological nuances and special considerations that are important in replicating this method are detailed in Table 3.

3 | RESULTS

The coding framework was used on the Tayside data set to produce an example stacked clustered bar chart (Figure) with the supporting raw data (Figure 2B).

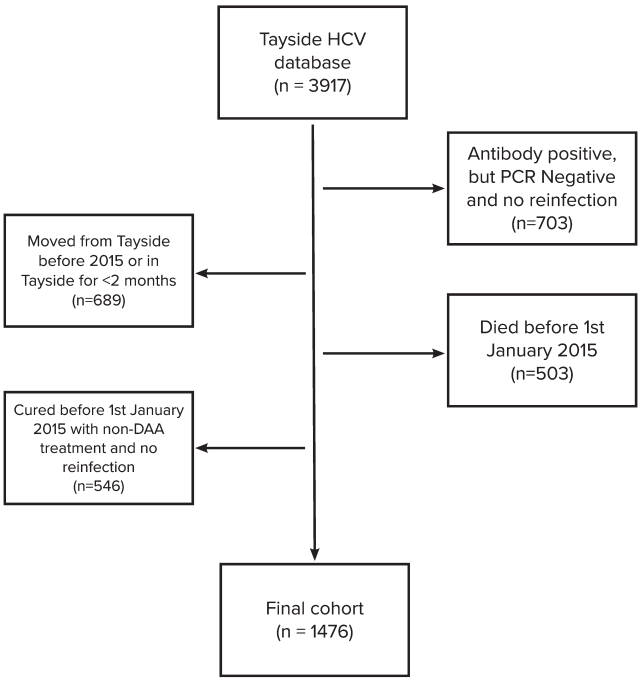


FIGURE 1 Cohort selection based on inclusion/exclusion criteria

Similarly to previous methods used, this method of displaying a cascade of care communicates the basic disease control stages: Diagnosis, Treatment and Cure. It provides a cumulative overview of the epidemic's progression during a period of time while also allowing for yearly comparison of the disease control stages.

Conversion rates, which indicate the percentage of people per year who move from diagnosis to treatment or cure, help to note overall progression towards defined targets and identify specific periods of success or struggle in the elimination efforts. In Tayside, diagnosis-to-treatment rates went from 19% (2015) to 50% (2019) and diagnosis-to-cure rates went from 18% (2015) to 49% (2019). Both diagnosis-to-treatment and diagnosis-to-cure rates saw the most significant rise from 2016 to 2017.

The method also provides a variety of nuance and distinction within each stage by offering 12 sub-stages of the cascade instead of the usual 3 (Diagnosis, Treatment and Cure). All of the following numerical figures for Tayside are expressed as averages from 2015 to 2019 unless otherwise specified.

Firstly, those who are unsuitable for treatment for clinical reasons will not progress through the cascade and are important to distinguish. Patients unsuitable for treatment include those that are palliating with advanced disease from other organs or those in which DAAs are contraindicated. In Tayside, 2% of diagnosed patients fall in this category.

Secondly, previously diagnosed patients and newly diagnosed patients are stratified both at the Diagnosis and Treatment stages. This is useful in clarifying the portion of patients with new diagnoses each year and to identify barriers in progressing new or previously diagnosed patients from Diagnosis to Treatment. In Tayside, the number of newly diagnosed patients is broadly similar year-on-year while the number of previously diagnosed patients decreases. Each year, 34% of newly diagnosed patients and 29% of previously diagnosed patients enter treatment. Newly diagnosed patients progressing to treatment increased from 12% (2015) to 60% (2019), and previously diagnosed patients progressing to treatment increased from 19% (2015) to 36% (2019).

Thirdly, unsuccessful and incomplete treatments are evidenced to clarify whether efforts need to be put into improving treatment types or increasing treatment compliance, respectively. In Tayside, 3% of treatment courses are unsuccessful and 6% of courses are incomplete. It is interesting to note that 23 people who did not complete treatment still achieved SVR. Of these, 1 patient partially completed a 24-week course of interferon [8 weeks], 8 partially completed an 8-week course of DAAs (Range = 2-7 weeks, Median = 4.5 weeks), 13 partially completed a 12-week course of DAAs (Range = 1-11 weeks, Median = 6 weeks), and 1 was unclear.

Fourthly, the portion of patients who have completed treatment but do not have a confirmed SVR is shown to provide information on patients that require follow-up. In Tayside, the service is still attempting to follow-up 5% of patients to confirm their post-treatment SVR status.

Lastly, deaths and patients that relocate are shown at each stage of the cascade. In Tayside, 4% of patients died and 2% moved each year.

TABLE 2 Coding framework

Category	Code	Definition
Diagnosis	Previous Diagnosis	Patients with an active HCV infection, first diagnosed before the given year that has not been treated successfully or spontaneously resolved
	New Diagnosis	Patients with an active HCV infection, first diagnosed at any point in the given year
	Can't Treat	Patients with an active HCV infection first diagnosed at any point in the given year that are unsuitable for treatment, usually for palliative reasons
	Moved	Patients with an active HCV infection first diagnosed at any point in the given year or beforehand that has moved before progressing to treatment
	Dead	Patients with an active HCV infection first diagnosed at any point in the given year or beforehand that has died before progressing to treatment
Treatment	Treatment - Previous Diagnosis	Treatment of a patient with an active HCV infection, first diagnosed before the given year that has not been treated successfully or spontaneously resolved
	Treatment - New Diagnosis	Treatment of a patient with an active HCV infection, first diagnosed at any point in the given year
	Treatment Unsuccessful	Unsuccessful treatment of a patient with an active HCV infection first diagnosed at any point in the given year or beforehand
	Treatment Incomplete	Incomplete treatment of a patient with an active HCV infection first diagnosed at any point in the given year or beforehand
	Moved	Patients with an active HCV infection treated at any point in the given year that has moved before progressing to cure
	Dead	Patients with an active HCV infection treated at any point in the given year that has died before progressing to cure
Cure	Cure	Patients who have achieved a clear Sustained Virologic Response (SVR), defined by HCV RNA below the lower level of detection, 12 weeks post-treatment; assigned to the year the treatment started
	Spontaneously Resolved	Patients who have a negative PCR test after previously having a positive PCR test but have not accessed treatment; assigned to the year of the negative test.
	Unknown SVR	Patients who have completed treatment, but their SVR status has not been confirmed; assigned to the year the treatment started
	Moved	Patients who have moved after completing treatment but before confirming they have achieved SVR; assigned to the year the treatment started
	Dead	Patients who have died after completing treatment but before confirming they have achieved SVR; assigned to the year the treatment started

4 | DISCUSSION

The coding framework suggested in this paper could be applied across healthcare systems to add nuance to stages of the cascade and to standardize definitions. This could facilitate the comparison across settings and systems, providing a potential reporting method the WHO might suggest to countries tracking their epidemics. An example of how the framework can be practically applied to any system's HCV data can be found in Appendix 1.

The proposed stacked clustered bar chart displays the cascade of care data in a way that relays yearly comparisons of an epidemic, cumulative progression over time, nuance between disease control stages and relation to elimination targets. It provides insights into how well people are moving through the cascade towards Cure, what initiatives are successful, and where challenges may be. This has key implications for health care planners and commissioners that want a deeper understanding of what is fuelling or hindering the local epidemic.

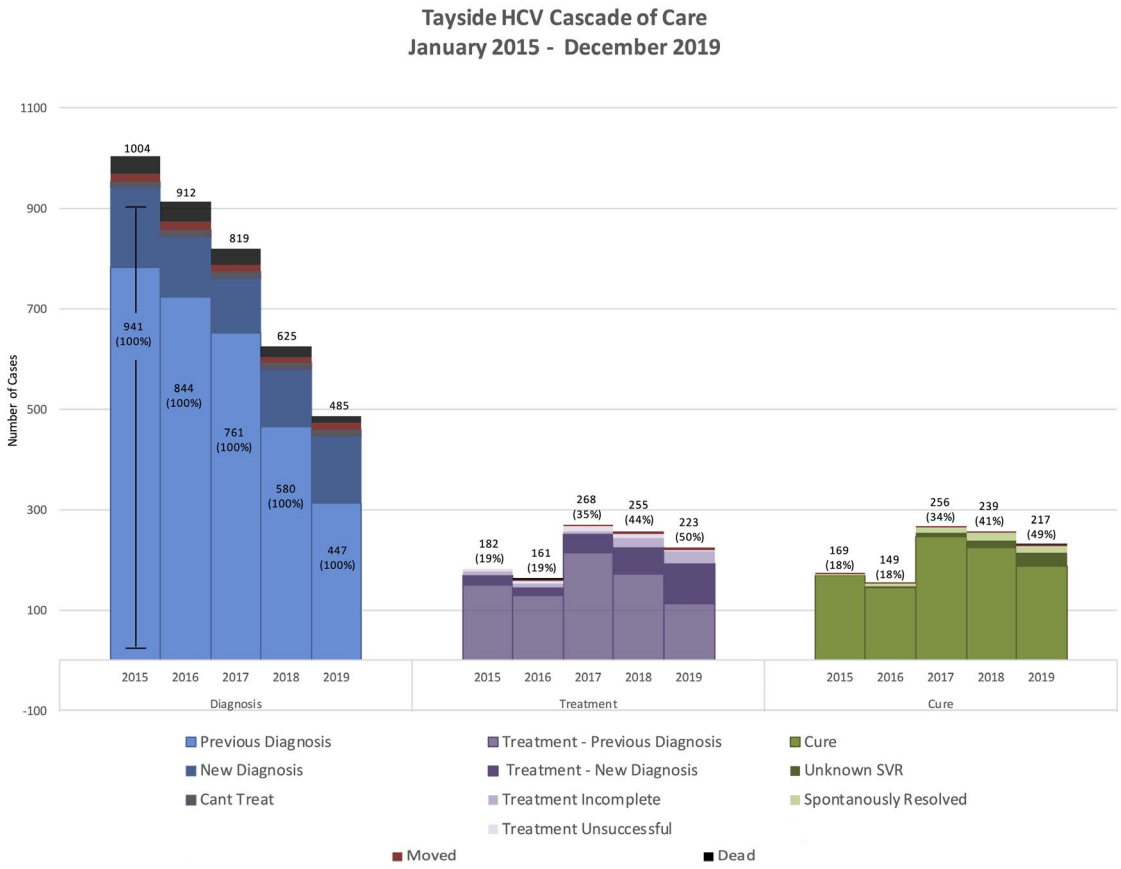
TABLE 3 Methodological nuances and special considerations

Diagnosis	Reinfections, whether in the same year or in subsequent years, are coded separately as individual infections. Patients with a positive DBST and negative PCR taken on the same day are considered negative as PCR is a more specific test. The small number of patients that are diagnosed in Tayside, move away and return to Tayside at a later date with an active infection are first coded as "New Diagnosis" and upon return coded as "Diagnosis Carrier."
Treatment	Though rare, multiple treatments for the same infection, whether in the same year or in subsequent years, are coded separately as individual treatments. Patients coded as "Treatment Unsuccessful" or "Treatment Incomplete" without a confirmed SVR for one year are coded as "Previous Diagnosis" for the successive year as they had not cleared the virus and are still pending a successful treatment. Though it is difficult to distinguish between a spontaneous resolution + reinfection or if the treatment was unsuccessful without genotyping each sample, patients who have a continually high viral load who have completed treatment without an SVR are coded as "Treatment Unsuccessful." Some samples are genotyped and if there is a distinct change in genotype, the cases are coded as two separate infections. Diagnosis-to-treatment rates are calculated by all patients in a specific year that are at the treatment stage ("[Treatment] − [Previous Diagnosis]" + "[Treatment] − [New Diagnosis]" + "[Treatment Unsuccessful]" + "[Treatment Incomplete]" + "[Treatment] − [Moved]" + "[Treatment] − [Dead]") divided by "[Previous Diagnosis]" + "[New Diagnosis]" for that same year. New Diagnosis Treatment and Previous Diagnosis Treatment rates are calculated by dividing "[Treatment] − [New Diagnosis]" by "[New Diagnosis]" and "[Treatment] − [Previous Diagnosis]" by "[Previous Diagnosis]", respectively. Unsuccessful and Incomplete Treatment proportions are calculated by dividing "[Treatment Unsuccessful]" or "[Treatment Incomplete]" by "[Treatment] − [Previous Diagnosis]" + "[Treatment] − [New Diagnosis]" + "[Treatment Unsuccessful]" + "[Treatment Incomplete]."
Cure	Cured cases are coded in the year that they started treatment. Since very high real world SVR rates have been observed in patients who completed treatment, patients with an End of Treatment Negative result are coded as achieving "Cure." Patients who have completed treatment but have not returned for SVR bloods are coded as "Unknown SVR" each year until they either have SVR bloods or a new PCR positive test, at which point they will again be coded as "Diagnosis." Patients that do not complete treatment but achieve SVR are coded as "Treatment Incomplete" and "Cure" Patients coded as "Dead" at the cured stage have completed treatment and are awaiting SVR bloods when they pass. Diagnosis-to-cure rates are calculated by "[Cure]" + "[Unknown SVR]" + "[Cure] − [Moved]" + "[Cure] − [Dead]" from a specific year divided by "[Previous Diagnosis]" + "[New Diagnosis]" for that same year. Unknown SVR rates are calculated by "[Unknown SVR]" divided by "[Cure]" + "[Unknown SVR]."
General	Deceased patients are coded as "Dead" within the last stage of the cascade that they completed in the year that they passed. Patients that move away from the region are coded as "Moved" within the last stage of the cascade that they moved.

Having used the method to analyse the Tayside data, it was evident that the area has been successful at both managing and tracking the local HCV epidemic. This may be attributed to their quick transition from interferon-based treatments to DAAs in 2015 and universal access to treatment provided for virtually all those infected. Tayside has utilized innovative testing and treatment pathways, some of which are located within community pharmacies and harm-reduction centres, to widen access to services at each stage of the cascade.[13-15] As in many settings, there are continuing challenges in providing services to those that are hardest to reach, such as those that frequently relocate or those that may not regularly engage with healthcare services.

Beyond Tayside, the method proposed in this paper can be implemented with basic spreadsheet tools that have pivot table and graphing functions. While the method, as described here, has been created to meet Tayside's needs using their rich data collection and

(A)



(B)

		Diagnosis					Treatment						Cure					Total	% Eligible Treated or Cured
		Previous Diagnosis	New Diagnosis	Cant Treat	Moved	Dead	Treatment - Previous Diagnosis	Treatment - New Diagnosis	Treatment Un-successful	Treatment Incomplete	Moved	Dead	Cure	Spontanously Resolved	Unknown SVR	Moved	Dead		
Diagnosis	2015	783	158	12	15	36												1004	100%
	2016	723	121	14	15	39												912	100%
	2017	652	109	14	11	33												819	100%
	2018	465	115	13	9	23												625	100%
	2019	313	134	13	12	13												485	100%
Treatment	2015						150	19	7	6	0	0						182	19.3%
	2016						129	16	6	7	1	2						161	19.1%
	2017						213	39	10	5	1	0						268	35.2%
	2018						171	54	7	19	4	0						255	44.0%
	2019						113	80	2	24	4	0						223	49.9%
Cure	2015												167	4	1	0	1	173	18.0%
	2016												144	7	2	0	3	156	17.7%
	2017												246	11	8	0	2	267	33.6%
	2018												223	16	14	0	2	255	41.2%
	2019												186	14	27	1	3	231	48.5%

FIGURE 2 A, 2015-2019 Tayside cascade of care. B, 2015-2019 Tayside raw data

storage processes, the method is malleable and could be adapted to other settings. Areas with less robust data can combine or remove codes to produce a more simplified version of the CoC, though this may impact the nuance and utility of the information. Similarly, new codes, such as reinfections, could be developed if useful to that local setting. Adding codes provides more helpful detail; however, it also increases the burden of data collection, adds complexity to the chart and loses the standardization of definitions. Further research is warranted to understand how this method might be applied in various healthcare settings with different diagnosis pathways, treatment services and levels of data keeping.

In conclusion, overall, this project proposes a novel way of codifying and displaying cascades of care data that relays yearly comparisons of an epidemic, overall progression over time, nuance within disease control stages and progress towards elimination targets. The coding framework can be used to standardize definitions across settings and the stacked clustered bar chart improves service evaluation to offer insights to healthcare planners who want a comprehensive understanding of what fuels or hinders a local cascade. More broadly, it can facilitate knowledge exchange across global health systems and offer a new way to track global infectious epidemics.

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CONFLICT OF INTEREST

CB, MC, EMR: None; JFD: honoraria for lectures and research grants from Janssen-Cilag, Roche, Merck Sharp & Dohme, AbbVie, Bristol-Myers Squibb and Gilead Sciences outside the submitted work.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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