A Roadmap for conducting psychosocial research in epidemiological studies: perspectives of cohort study principal investigators

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ABSTRACT

Background Psychosocial adversity disproportionately affects racial/ethnic and socioeconomic minorities in the USA, and therefore understanding the mechanisms through which psychosocial stress and resilience influence human health can provide meaningful insights into addressing US health disparities. Despite this promise, psychosocial factors are infrequently and unsystematically collected in the US prospective cohort studies.

Methods We sought to understand prospective cohort principal investigators’ (PIs’) attitudes regarding the importance of psychosocial influences on disease aetiology, in order to identify barriers and opportunities for greater inclusion of these domains in high-quality epidemiological research. One-hour, semi-structured qualitative interviews were conducted with 20 PIs representing 24 US prospective cohort studies funded by the National Institutes of Health (NIH), collectively capturing health data on 1.25 of every 100 American adults. A hypothesis-free, grounded theory approach was used to analyse and interpret interview data.

Results Most cohort PIs view psychosocial factors as an important research area to further our understanding of disease aetiology and agree that this research will be crucial for future public health innovations. Virtually all PIs emphasised that future psychosocial research will need to elucidate biological and behavioural mechanisms in order to be taken seriously by the epidemiological community more broadly. A lack of pertinent funding mechanisms and a lack of consensus on optimal scales and measures of psychosocial factors were identified as additional barriers to advancing psychosocial research.

Conclusions Our interviews emphasised the need for: (1) high-quality, longitudinal studies that investigate biological mechanisms and pathways through which psychosocial factors influence health, (2) effort among epidemiological cohorts to broaden and harmonise the measures they use across cohorts, to facilitate replication of results and (3) the need for targeted funding opportunities from NIH and other grant-making institutions to study these domains.

INTRODUCTION

Psychosocial factors encompass a broad set of experiences, including childhood adversity, isolation and loneliness, job-related stress, discrimination, trauma, religious and spiritual experiences, social support, healthy neighbourhoods and many other dimensions of life. While acute stressors normally elicit a healthy and adaptive stress response, severe or prolonged psychosocial stress can lead to long-term dysregulation of the stress reactivity system and disease.1,2 In particular, psychosocial stress has been implicated as a factor contributing to cardiovascular disease,3,4 hypertension,5 type 2 diabetes,6 obesity7 and cancer,8 among other conditions. Likewise, positive psychosocial factors are also important sources of resilience, support and engagement that can have positive impacts on mitigating stress and improving health.9-11

Despite the important role that psychosocial factors may play in disease aetiology, they are not often assessed comprehensively in epidemiological research, particularly within prospective cohort studies. Furthermore, a
lack of precise and operational definitions and clinical cut-off points for many psychosocial exposures has kept them from being incorporated more routinely into clinical guidelines and practice.12 13 The influence of psychosocial factors on disease aetiology potentially encompasses both acute and chronic experiences, occurring throughout the life course in both childhood and adulthood that may associate with human disease through many different biological pathways.6 14  Since psychosocial experiences are complex phenomena that span many dimensions and time points within a person’s life, this poses difficulties for quantitative assessment in epidemiological research. It is therefore important that epidemiological investigators critically evaluate the measurement and investigation of these domains in a systematic and thoughtful way.

Given that psychosocial adversity and stress are often experienced more frequently by racial/ethnic and socioeconomic minority populations in the USA,15 understanding the mechanisms through which psychosocial stress influences human health may also provide crucial insight into the production of health disparities in the USA. Psychosocial stress may function both as a key factor driving disproportionate burdens of disease among underrepresented populations16–18 and also serve as a key mediator or pathway through which experiences of inequality—such as difficult socioeconomic environments19 20 or poor sleep,21 among others—influence disease or disease-related behaviours. Likewise, fostering tools for psychosocial resilience and community building among underrepresented populations may also have a positive impact on health inequality.11

In order to identify barriers and opportunities for greater inclusion of these psychosocial domains in high-quality epidemiological research, we conducted qualitative interviews with 20 principal investigators (PIs) representing 24 different US prospective cohort studies funded by the National Institutes of Health (NIH). These interviews were used to probe PIs’ beliefs and opinions on the impact of psychosocial factors on health and were also used to identify the evidence they require to see before adding additional assessments of psychosocial factors in future waves of data collection within their cohorts. Taken together, the qualitative results that follow from these interviews inform a theory of change that provides a roadmap for future psychosocial research methods that we theorise will generate more prominent and impactful psychosocial investigations within epidemiological research.

**METHODS**

**Defining ‘psychosocial’**

Psychosocial research encompasses many possible topics and is used in myriad studies, although definitions are rarely offered. In this article, we begin by offering a definition, or at least a point of reference, that will serve as a useful starting point for understanding psychosocial dimensions of life. The American Psychological Association (APA) Dictionary of Psychology22 lists several different definitions that can help us triangulate a working meaning. ‘Psychosocial factors’ are defined as ‘social, cultural and environmental phenomena and influences that affect mental health and behaviour’ (figure 1). A ‘psychosocial stressor’, more specifically, is defined by the APA as ‘a life situation that creates an unusual or intense level of stress that may contribute to the development or aggravation of mental disorder, illness or maladaptive behaviour. Examples of psychosocial stressors include divorce, the death of a child, prolonged illness, unwanted change of residence, a natural catastrophe or a highly competitive work situation’.

This definition of psychosocial is broad and encompasses experiences throughout the life course. It is important to note that the term psychosocial in itself does not refer just to adverse life events but more broadly to the confluence of social, cultural and environmental factors that come together to affect our biology, physiology and psychology. Consequently, the term psychosocial captures both negative stressors and positive sources of resilience, engagement and community. This includes factors such as social support, religion and/or spirituality (R/S) and healthy neighbourhood conditions.

**Research team**

The research team members carrying out interviews (AS and TB, both women, PhD-level investigators) and data analysis (AS, TB, MAA, BS and SNP, the final three of which were masters-level/predoctoral-level researchers) have training and experience in diverse disciplines,
including qualitative, clinical and epidemiological research. The team was thus ideally suited to anticipate and address the dual demands of both maintaining qualitative rigour while also trying to elicit and analyse data intended to engage an epidemiological audience.

AS is a health researcher who directs a research centre that conducts transdisciplinary research aimed at elucidating the underlying causes of health disparities, identifying novel strategies to reduce health disparities and addressing ethical and social issues in genomic research. TB is a radiation oncologist with a longstanding interest in understanding the ways in which patients’ religious or spiritual beliefs and practices influence their healthcare decision-making, particularly at the end of life. MAA is a medical anthropologist and population health researcher currently in the final year of a PhD in population health, and BS is an MD candidate and medical geneticist. Both MAA and BS have worked with AS over the past 5 years to conduct epidemiological and population health research on health inequality, with a particular focus on investigating psychosocial factors. SNP has training in cultural anthropology and is a DO candidate. She has conducted research with TB for over 2 years focused on understanding the impact of R/S on health.

The research team sought to mitigate bias stemming from any prior beliefs or hypotheses the investigators brought to the study by employing good interviewing practices in which questions were asked without providing examples or steering the discussion in ways that were apt to introduce bias. Data coding and analysis were carried out using a hypothesis-free, grounded theory approach such that themes and theories presented in this article were only those that emerged from the empirical data and are not reflective of previous perspectives or interests of the investigators. These methods, in addition to data triangulation procedures, are described further in the Data analysis section.

Participants and recruitment

This study was carried out as part of a larger project investigating the perspectives of PIs on both psychosocial and R/S influences on health. PIs were contacted, recruited and then interviewed about these two topics simultaneously. The results concerning PIs’ views on the role R/S specifically are published in a separate manuscript.23 Because of our interest in generating new knowledge useful for reducing health disparities, we first developed an initial list of NIH-funded cohort studies that included large, national samples of racial/ethnic minority communities. Additional cohorts were identified through the published literature, NIH resources and consultation with epidemiologist colleagues. We then developed a ranked list of 30 cohort studies based on how well they met the following criteria: (1) diverse racial/ethnic cohort composition, (2) long duration of competitive funding (as a proxy for influence of the PI), (3) many diverse clinical conditions covered and (4) inclusion of large, nationally representative samples of cohort participants.

The PI of each of these 30 studies was invited via email to participate in this qualitative study. None of the study investigators had had a previous relationship with the PIs. Telephone calls were scheduled with those interested in learning more, during which PIs were provided with additional information about the study to facilitate informed consent and again invited to be interviewed then or on a future date of their choosing. PIs who agreed to be interviewed were offered a US$100 honorarium. We followed these procedures until we reached our study goal of 20 PI interviews. Only one PI with whom we discussed the study declined to participate. All but two participating PIs refused the honorarium. Based on our prior work,24–29 we anticipated that 20 interviews would be a sufficient number to achieve thematic saturation.

Data collection

All 1-hour, semi-structured PI interviews were conducted in 2015 by the PI of our qualitative study (AS), with a subset of interviews conducted jointly by two members of the study team (AS and TB). During interviews, PIs were invited to articulate their own understanding of psychosocial research and psychosocial influences on health in the broadest possible sense and were not provided a definition by interviewers. PIs were not instructed to focus on specific psychosocial experiences or variables, and therefore unless specific types of experiences are given as examples in a PI’s response, we interpret their answers to refer generally to the whole field of psychosocial factors. Interview questions addressed: (1) PIs’ experiences with and exposure to research addressing psychosocial influences on health, (2) reasons why their cohort has collected particular psychosocial measures in the past, (3) assessment of the quality and value of existing psychosocial research, (4) assessment of the importance of psychosocial factors in understanding disease aetiology, (5) beliefs regarding the pathways or mechanisms through which they imagine psychosocial factors might operate to affect human health, if at all and (6) the evidence they would need to see before being willing to invest additional cohort resources in collecting new psychosocial measures.

Data analysis

All interviews were recorded and transcribed. Transcripts were analysed using a grounded theory approach.30 31 The interviewers and two research assistants (RAs; BS and SNP) independently coded 40% of transcripts and identified key themes. Coding discrepancies were addressed through discussion, comparison of the raw data and refinement of code definitions. The interviewers then finalised the preliminary coding scheme. The remaining transcripts were coded independently by the RAs, using Atlas.ti software (V.5.0) and any emergent themes or discrepancies were brought to the investigators for resolution. Data were analysed using content analysis to identify major concepts and themes and axial coding was used to group and connect related data.29 31 32 Within each
topic area, we identified statements characteristic of the majority of those interviewed as well as statements from those with divergent views. The quotes included in this report are illustrative of sentiments expressed by several PIs, unless otherwise noted. No repeated interviews were carried out, and participants were not provided with transcripts or findings to provide comments or feedback.

Many steps were taken to maximise dependability (consistency, reliability) and credibility (the truth of findings, internal validity) of study conclusions. We incorporated triangulation at two levels. First, we used a multidisciplinary research team for coding and analysis (investigator triangulation). All coding was done using a grounded theory approach, wherein investigators identified themes that emerged from the empirical data irrespective of their own hypotheses, research interests or priorities. The Kappa score for assessing congruence of coding between coders was 0.95, indicating an extremely high interrater reliability. This strongly suggests that the coding schema developed and applied to interview transcripts reflect themes emergent and plainly evident in the transcripts and do not reflect investigator bias or investigators projecting their own epistemological viewpoints onto the information provided by the informants. Second, we included PI participants from diverse communities and disciplines, whose cohort studies also include participants from diverse racial/ethnic communities and geographical regions of the country (data triangulation). This ensured that any significant themes found were reflective of a consistent and broad viewpoint across PIs representing many different kinds of NIH-funded cohort studies.

Patient and public involvement

As this was a targeted investigation into the perspectives of NIH-funded cohort study PIs, no patients or members of the public were involved in the design or recruitment of our study, nor in the dissemination of results. Our semi-structured interview guide was developed by AS, with input from the study team and several investigators participating in the National Consortium on Psychosocial Stress, Spirituality, and Health.

RESULTS

The final study sample of 20 PIs included men and women from several different racial/ethnic communities, although the vast majority were white. PIs represented a wide range of ages, although few were younger than 55 years old. Most PIs had led only one prospective cohort study in their career, although some had served as PI for more than one study. Collectively, the 20 PIs interviewed for this study represent longitudinal health data on nearly 3.2 million individuals across 24 cohorts or roughly 1.25 out of every 100 adults in the USA aged 18 or over. This includes data on every major racial group in the USA, including approximately 405,000 African Americans and 116,000 Hispanics/Latinos (figure 2).

Importance of the psychosocial domain

PIs shared similar views regarding the importance of psychosocial influences on health outcomes. When asked about the importance of psychosocial measures more broadly, one PI responded with:

I mean, I think it is very, very important. We’ve tried to pay a lot of attention to it in our own cohort…I think it’s very important to pay a lot of attention to this, because I feel that many psychosocial variables are definitely modifying factors for disease risk, and can also be causally associated.

PIs with clinical experience often cited their observations of the influence of psychosocial experience on their patients’ outcomes: ‘I think it’s based on my clinical experience…if you don’t address the psychosocial factors, you’ll never be able to help improve that person’s treatment, and their care for diabetes’. Those with clinical experience also seemed to appreciate the complex ways in which psychosocial factors interact with other ‘traditional’ risk factors:

Certainly, my feeling is that there’s probably some complex interplay between psychosocial factors and, for lack of a better word, more traditional factors—say, for instance, a blood level of cholesterol or blood pressure…In my clinic, I can certainly see that some of these psychosocial factors have enormous impact on the other potent, traditional risk factors.

Others viewed psychosocial measures in general as ‘soft’ measures that would never be as informative as ‘hard’ biological measures, but even these PIs believed that to ignore psychosocial influences would be a mistake:

This [psychosocial influences] is not a solid measure of exposure. But I do think that to ignore it, when you’re talking about symptoms and presentation of disease, is a mistake, because it’s all together…I think it all goes together to create this person’s sense of well-being, and you can’t ignore it.

Others noted tensions within the field of epidemiology regarding the importance of psychosocial factors in disease etiology, particularly regarding the extent to
which psychosocial factors were captured in other measures of behaviour or social support already collected. As one PI explained:

I think there’s two camps...The sceptics feel it’s not an independent risk factor, and you can account for it with all the other factors and behaviours like smoking, alcohol use, etc. But there’s a very strong camp that believe that these are upstream of the lifestyle behaviours, and if you don’t measure them correctly, you may be artificially saying that they are all explained by behaviours, and that they may actually be independently related to disease outcomes.

Despite a general acceptance of the importance of psychosocial factors in health expressed by the majority of PIs, some were more positive about certain psychosocial domains over others. While PIs were often quick to accept the importance of measuring factors such as social support, abuse and discrimination, many were far less certain about the contribution of R/S as a source of psychosocial resilience, for example, since it has been less extensively studied in cohort studies. Among our PI informants, three believed that R/S were not important to study in research on human health, eight were open to the possibility that R/S may be important to health but believed that the ‘jury is still out’, and nine felt that R/S likely had an important impact on health.

The need for psychosocial research using clinically relevant biomarkers
The vast majority of PIs suggested that for future psychosocial research to gain greater currency among epidemiologists, it would need to explore clinically relevant biomarkers and biological mechanisms. As one PI put it, ‘I think the emphasis today in epidemiological sciences is to delineate a clear biological mechanism’. Some offered ideas about creative avenues for exploring these relationships: ‘I would love to see studies on the effect of psychosocial stress on the microbiome, because of stress’s influence on the immune system’.

When asked where they see the field of psychosocial research going in the future, one PI responded, I think it is moving into trying to be more anchored in actual biologic changes...to identify people who are actually more likely to have a biologic response in relation to some external stressor’. One PI noted that recent studies investigating psychosocial stress in relationship to biological variables are changing epidemiologists’ opinions on the importance of psychosocial stress to health:

Studying psychosocial factors and stressors is relatively new, and [was] met with a lot of scepticism until fairly recently... But I think what’s changed...[is] there’s now biological evidence that stressors may affect various biomarkers.

Another PI emphasised that psychosocial research should ideally be framed in terms of a biological pathway:

I wouldn’t require that you would have the whole pathway—that is, exposure to intermediates to health outcome—because that’s probably the kind of link we’re looking for in studies. But having something between the intermediate and health outcome, and having something between the determinant and something along that initial pathway, I think would be very helpful to justify doing [psychosocial] measures in a cohort study.

Although all PIs discussed the value and contribution of conducting future research to elucidate the biological mechanisms through which psychosocial factors operate, several also had concerns about potential directions this kind of research could take when connected to the health of minority and underrepresented communities. As one PI articulated, it is ‘a little frightening to think about genes and behaviour, or genes and things in the psychological realm. You know, some sinister images can pop up...it frightens some people that, you know, you can look at a genome, characterise somebody, and discriminate against them’. Other PIs shared similar worries about genomics research with a focus on psychosocial factors. The concern was that if researchers establish correlations between genetic variants (or other biological characteristics) and psychosocial factors such as educational attainment, living in a poor neighbourhood, experiencing discrimination or other factors, that these results might be used to justify discrimination against these groups. In other words, these sorts of results might be used by those who do not understand the nuances and limitations of these research findings to try to claim that certain groups in society who experience adversity or inequality are genetically or biologically inferior.

Psychosocial research as an important domain for potential interventions
Roughly half of the PIs interviewed also discussed psychosocial research as potentially helpful in developing public health interventions. One PI articulated this particularly well:

We’ve had half a century of risk factor epidemiology that tends to focus on the individual as the driver of behaviour change. I think this field of stress and psychosocial stress is one that can help us look at the social context and other environments in which people live, and help us think about interventions.

Another PI not only echoed this enthusiasm but also expressed concerns about how to actually operationalise insights into psychosocial research for public benefit. As he explained, ‘So to the extent that observing that racial discrimination increases stress and can impact high blood pressure...that’s a useful, almost intuitive observation. But then what?...How do we then break that influence on health?’

PIS’ abilities to envision how psychosocial research would translate into improved public health interventions
varied by the type of psychosocial domain discussed. Some PIs, for example, had difficulty seeing how R/S research could be used to develop interventions to improve health. As one PI explained:

With [R/S research on church attendance], I just wonder what the message is…Is the message that people should find God? Or go to church more often? From a personal background, I would feel uncomfortable with public health messages that had to do with religious matters.

**Challenges in the field**

Despite expressing uniform appreciation for the potential of psychosocial factors influencing disease onset or survival, many PIs described a number of circumstances that they see as inhibiting their own cohorts, and the larger epidemiological community, from engaging in robust assessments of psychosocial factors.

**Challenging funding landscapes**

Several PIs mentioned that despite their own interest or the interest of their colleagues, a lack of relevant funding mechanisms, or even a lack of certainty about future NIH cohort funding in general, has prevented efforts to investigate psychosocial factors. Several made off-hand comments similar to this one: ‘Oh, we are always open to new projects. So we would be happy to ask questions if there was funding available’. Many PIs also described that their funding organisations had specific scientific priorities and expectations for the parameters of their cohort’s questionnaires, which would limit their ability to add in survey questions on psychosocial stress. Several cohort PIs also noted that they do not currently have funding from NIH lined up for another wave of data collection.

**Reproducibility and consensus surrounding measures of psychosocial factors**

Several PIs noted that for researchers to be able to produce robust research on psychosocial variables and health, it would be a priority that multiple cohorts collect the same psychosocial measures. Describing the field of psychosocial research at large, one PI recounted, ‘My sense is that…it’s still very broad. And different people are doing different types of psychosocial stressors…I’m hoping that the field might narrow a little bit if we’re able to do this kind of linkage [between cohort studies]’.

PIs often articulated that this would necessitate pooled analyses across cohorts and racial/ethnic groups:

I think the kind of data that I would like to see are large, multicentric, multiethnic cohorts, with reasonable duration of power—of follow-up, with adequate statistical power, with appropriate characterisation of the exposure with validated instruments, appropriate adjustment for multiple layers of confounding.

As another PI described, however, the downside is that ‘we always go back to the least common denominator when we pool. And to do gene environment interactions, you almost have to pool cohorts…You’re going to lose quality if people don’t ask the question in a manner that you can pool across studies’. Clearly, the lack of similar or harmonised psychosocial measures across multiple cohorts to facilitate larger scale, pooled analyses, is seen by most PIs as a limiting factor for current psychosocial research.

**DISCUSSION**

The PIs we interviewed almost unanimously agreed that future research on psychosocial domains is likely important to population health, but emphasised the need to elucidate the biological and behavioural mechanisms through which psychosocial factors impact health in order to convince the epidemiological community more broadly to invest resources in investigating psychosocial stress and resilience. To conduct this kind of rigorous psychosocial research using biomarkers and mechanisms, investigators will need to have access to both robust and clinically relevant biological data as well as comprehensive psychosocial, socioeconomic, behavioural and health outcome or clinical data on their study participants. Data are also needed at both the individual and neighbourhood levels to properly capture all of the dimensions of a person’s psychosocial environment. These comprehensive data are currently most reliably found in prospective cohort studies, but robust numbers of psychosocial measures are not yet found consistently across cohorts.

One striking finding from our study is the extent to which the selection of psychosocial measures to be collected by cohorts is a nonlinear process determined by the interests and biases of particular research teams. It seems that cohorts did not set out to systematically identify all psychosocial factors and domains that are important to health and thus should be included in their data collection efforts. Instead, cohorts seem to have only collected psychosocial factors if and when they support other analyses for more traditional outcome or lifestyle variables, or if an investigator within the cohort advocates for a particular psychosocial measure needed to support their research. Thus, successful psychosocial research depends on champions within established epidemiological cohorts who can convince colleagues to commit resources for collecting further psychosocial variables and completing psychosocial analyses.

Our interviews also showed that many cohort PIs see psychosocial research as an important area to investigate for developing potential public health interventions. Indeed, behavioural, lifestyle and resilience factors have been shown to mitigate the impact of stress on developing disease. Despite this enthusiasm exhibited by PIs, however, our interviews also highlighted challenges to the feasibility of this research. In particular, the lack of targeted funding and the lack of consensus on key measures to be collected and/or harmonised across
cohort studies were identified as primary barriers that need to be overcome to advance psychosocial research.

Our study had several limitations worth noting. While the 20 PIs interviewed represented diverse ethnicities, ages and clinical domains of interest, they may not fully capture the diversity in PIs’ attitudes towards psychosocial research. According to NIH websites, there are 70 cohort studies currently funded by the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI), and thus our results reflect the perspective of PIs from roughly a quarter of all NIH-funded cohorts. Future research could survey PIs nationally to quantitatively assess a broader array of perspectives. While we have outlined in this paper the types of research that will be persuasive to cohort PIs in evaluating psychosocial research, future research could also investigate PIs’ views on what the quantitative threshold—in terms of numbers of new studies, health conditions investigated or other criteria—might be for a persuasive evidence base that legitimises the investment of more cohort resources into psychosocial research. Furthermore, our grounded theory approach limited our analyses to the empirical data gathered and did not allow us to offer deeper interpretation or explanations for why PIs may hold the views that they reported. We also recognise that there may seem to be a methodological disconnect in conducting a qualitative, grounded theory study to provide insight to a quantitative, epidemiological audience. We believe, however, that in-depth interviews with cohort PIs are highly strategic approach that is essential to understanding the on-the-ground demands and challenges of conducting epidemiological research with cohort study data and is crucial to developing a theory of change for epidemiological psychosocial research. We further believe that our multidisciplinary team of investigators who have training and experience in both qualitative and epidemiological research have allowed us to bridge these two different methodological approaches and epistemologies.

Despite these limitations, this study provides the first assessment of cohort PIs’ attitudes and beliefs regarding the influence of psychosocial factors on disease aetiology and identifies challenges for the field of psychosocial research from the perspective of these thought leaders in epidemiology. Our results provide a strategic and pragmatic roadmap for future psychosocial researchers to draw upon in designing and proposing research studies to be conducted within cohort studies, and for identifying strategies to engage cohort study investigators in future research to advance knowledge regarding the role of psychosocial influences in disease aetiology.

CONCLUSION
Looking forward, our interviews with cohort PIs emphasised that (1) future research will need to investigate biological and behavioural pathways through which psychosocial factors influence disease, (2) funding bodies need to create funding mechanisms and requests for proposals that specifically support these types of analyses as a scientific priority and (3) psychosocial research will need to be carried out with a focus on building consensus within the greater epidemiological community regarding the most important psychosocial factors to human health and the best measures for capturing these factors, in order to facilitate replication of results and multicohort analyses. PIs also emphasised that future psychosocial research that follows these steps may be particularly impactful in identifying novel public health interventions. By understanding the mechanisms through which psychosocial factors—including both stress and resources for resilience—operate to affect disease across diverse populations, researchers will not only gain new insight into the aetiology of many chronic diseases but will also generate new insight into how health disparities in the USA are produced and identify new leverage points for addressing them.

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