



Public Health Service
DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Disease Control and Prevention (CDC)

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Mr. Jim McClelland, Executive Director
Drug Treatment, Prevention, and Enforcement Commission
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Dear Director McClelland,

CDC is grateful for the work of this Commission and for its leadership in reducing injurious opioid use in Indiana. We want to ensure the Commission has the best available data to inform its recommendations and actions. To that end, CDC wishes to clarify certain preliminary results of a study we conducted of the syringe services program (SSP) in Scott County; specifically the finding that persons using the SSP increased their median daily number of injections from five to nine as the this program was getting started. In the Commission's Task Force Final Report published in the fall of 2016, these results were unfortunately mischaracterized as evidence that the SSP had led to increased drug use.¹ This conclusion is erroneous as described below. CDC respectfully asks the Commission to consider revising this error in the Task Force's 2016 report and adding this letter to the official record to ensure correct characterization of these data when they are referenced in the report.

The study in question was designed to assess the impact on injection behaviors of a first-of-its-kind emergency SSP established in Scott County during the 2015 HIV and hepatitis C outbreak in that county. This study and another, which occurred very early in the outbreak investigation, were conducted jointly by Scott County Health Department, the Indiana State Department of Health, Indiana University, and the U.S. Centers for Disease Control and Prevention. In the first study, scientists measured self-reported changes in injection behavior among 148 persons who injected drugs (PWID) before and after they enrolled in the SSP. In the second study, scientists conducted qualitative in-depth interviews with 56 PWID in Scott County to provide context for the changes measured in the first study and to better understand how the drug of choice in this community, OPANA® ER, was being used.

The first study found strong evidence that after joining the SSP, access to sterile injection equipment significantly decreased unsafe injection behaviors that could transmit HIV and hepatitis C. The second study showed that in this context, drug use among PWID who joined the SSP remained essentially stable. Five of 56 people interviewed had reduced or discontinued drug use, and only one person reported increased drug use due to tolerance and increasing need.

1. Final Report, Governor's Task Force on Drug Enforcement, Treatment, and Prevention, State of Indiana, Fall 2019
http://www.in.gov/gtfdetp/files/Governors_Drug_Task_Force_Final_Report.pdf, page 10

CDC and our colleagues also learned that the number of times PWID in Scott County injected themselves was extremely high, on average 10-15 times per day, and in one extreme example up to 35 times per day. This high injection frequency was caused in large part by a chemical added by OPANA® ER's manufacturer to deter misuse of the drug through snorting or injection. The presence of this chemical deterrent made it difficult to dissolve OPANA® ER tablets. To dissolve tablets in a cooker to create a solution for injection, PWID often needed to add more than 100 cc of water, a volume that exceeded the capacity of the 100 cc syringes used most often in this community and in the U.S. To inject this entire drug-containing solution required administering more than one injection per each injection episode. Further, the process for dissolving OPANA® ER tablets left behind a visible residue in the cooker, which many PWID believed contained leftover drug. This residue prompted PWID to add more water to dissolve the residue, creating an additional dose that was then injected. Thus at each injection episode, PWID were injecting themselves 1-4 times. This is a very atypical practice. Other injected drugs, such as heroin, can be administered with a single injection. Due to OPANA® ER's short duration of action when injected (half-life 3-4 hours), PWID also had to inject frequently to prevent experiencing withdrawal symptoms, further adding to the total daily number of injections to which PWID were exposed.²

As CDC and our colleagues began to synthesize the data from these two studies, we recognized a paradox. Namely, during the first few months after the SSP was activated (and as described at a major international meeting of infectious disease experts in October 2015³ and cited in the Task Force's 2016 report) clients reported that their number of daily injections increased from five to nine. Yet our in-depth interviews indicated that drug use among PWID had remained stable during this time.

We now recognize that the data about number of injections in fact substantially underestimated PWID's true injection frequency. We have learned that this underestimation resulted from misunderstandings among both SSP staff and clients. At the SSP's outset, staff did not initially know (and would not have been expected to know based on available evidence at the time) that more than one injection took place each time a PWID injected OPANA® ER. They asked PWID how many times a day they injected in order to calculate the appropriate number of needles/syringes to dispense. As the SSP program matured, staff began to recognize that PWID were injecting multiple times at each injection episode. As a result, SSP staff improved their assessment of clients' needle/syringe needs by counting not just injection episodes but also number of injections per episode. SSP clients did not realize that sterile equipment was necessary for every injection, not just each time they used drugs; indeed, enrolling in the SSP may have been the first time many clients assessed their actual usage.

With time and experience, SSP staff helped clients understand that to achieve truly safe injection 100% of the time, clients needed to report a number of injections equal to the total number times they injected themselves with a needle each day. The increase in injection frequency from five to nine times per day that we observed during the first weeks the SSP's operation reflects this collective learning curve.

As stated on page 10 of the Task Force's 2016 report, "Despite these favorable indicators, participants also reported injecting drugs more often between their first and latest trips to the exchange,

2. The well-intentioned action by the manufacturer to deter abuse of OPANA® ER inadvertently increased public health risk and fueled the rapid spread of HIV in Scott County. As a result, the Food and Drug Administration recommended OPANA® ER be removed from the U.S. market and the manufacturer has complied

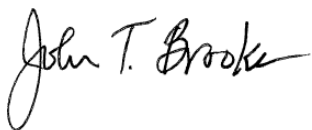
3. See: <https://idsa.confex.com/idsa/2015/webprogram/Session7425.html>. Also listed as reference #73 in the Task Force's Final Reports

with the median injection frequency rising from five to nine times per day.” This conclusion is incorrect. Rather, the apparent increase is most consistent with improved assessment of SSP clients’ injection frequency in an environment where we were learning that the true injection frequency was unprecedentedly high. PWID reported that their drug use remained stable, consistent with the well-established fact that SSPs do not increase drug use.^{4,5,6} As highlighted in the 2016 report from the U.S. Surgeon General, “Evaluation studies have clearly shown that needle/syringe exchange programs are effective in reducing HIV transmission and do not increase rates of community drug use.” We do not believe these data on injection frequency when considered in their full context are evidence to the contrary.

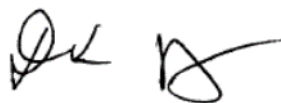
CDC hopes that this letter clarifies our finding that as the SSP in Scott County began operation, the apparent increase in injection frequency used to determine clients’ needle/syringe needs in no way indicated increased drug use among PWID accessing the program.

CDC welcomes any questions that you, the Commission, or its Task Force have regarding these studies. The findings have been compiled into a number of scientific papers that are in process of undergoing peer-reviewed publication.

Sincerely,



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4. U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General’s Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016

5. Wodak A, Cooney A. Do needle syringe programs reduce HIV infection among injecting drug users: a comprehensive review of the international evidence. *Substance use & misuse* 2006,**41**:777-813.

6. Groseclose SL, Weinstein B, Jones TS, Valleroy LA, Fehrs LJ, Kassler WJ. Impact of increased legal access to needles and syringes on practices of injecting-drug users and police officers-Connecticut, 1992-1993. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 1995,**10**:82-89.