Comment on "Life cycle comparison of environmental emissions from three disposal options for unused pharmaceuticals."

In their article on the life-cycle assessment (LCA) of disposal options for unwanted medications, Cook et al.[1] do not account for acute hazards posed to public health and safety. Their recommendation ("... we recommend trash disposal for unused pharmaceuticals") results from an oversimplified LCA that considers only environmental emissions. Also needing attention is the critical concern for preventing accidental poisonings, diversion, and abuse. The US EPA and the Drug Enforcement Administration (DEA) continue to recommend that consumers follow the White House Office of National Drug Control Policy (ONDCP) guidelines for disposal, as modified by the US Food and Drug Administration (FDA).[2] These can be summarized as: (1) for a limited number of drugs specified by the FDA, flush to sewers, (2) use drug take-back programs (supervised collection events) when available, and (3) use trash disposal when take-back programs are not available.

Exclusive use of domestic trash for drug disposal could lead to increased risks for consumers (especially children) as well as for trash collectors (as drug delivery devices with sharps also pose acute risks when discarded in trash). Although take-back programs are still not widely available, they do provide a marked advantage over trash disposal in helping to prevent accidental poisonings, diversion, and abuse (abuse of prescription drugs is the fastest-growing drug problem in the US[3]).

While it is generally acknowledged that design and implementation of efficient disposal options are needed for unwanted medications, the primary objective for any viable option must be to first protect human health and safety. This had been the major goal for the first federal guidance on drug disposal, issued in 2007 by the ONDCP, and for the ongoing efforts of the DEA in facilitating the disposal of unwanted drugs with periodic supervised collection events that can accept the return of controlled substances.[4]

Assessing the environmental impact of drug disposal options cannot be done without also assessing the exposure risks posed to humans. The two are inextricably linked. This is especially true given that imprudent disposal of certain drugs can pose hazards not just for people, but also for pets and wildlife scavengers; indeed, this was even noted in a reference[4] cited by the article. Collection of unwanted drugs by organized take-backs - coupled with flushing to sewers for select drugs - are both prudent approaches for drug disposal.

The LCA fails to note that the FDA recommends flushing to sewers as the disposal route for certain drugs with high abuse potential.[2] There are additional drugs not listed by the FDA for flushing that possess single-dose lethality for children; some of these medications are commonly available without a prescription.[5] Certain drugs can be lethal to children in whole-body doses as low as a milligram - one or more orders of magnitude more toxic than the most toxic pesticides available to consumers. Some of the more common medications that can be fatal to a 10-kg toddler ingesting only 1 or 2 tablets or teaspoons include: chloroquine, hydroxychloroquine, quinine, imipramine, desipramine, methyl salicylate, theophylline, thioridazine, and chlorpromazine. Opioids are commonly involved with fatal poisonings in children (especially hydrocodone, morphine, oxycodone, propoxyphene, and methadone).

Lethality is a major concern for both new and used transdermal delivery devices (especially certain medical patches).[5-7] Drugs with single-dose (or low-dose) lethality should never be left unsecured - wherever they are located. Disposal to trash can greatly increase this risk. To further emphasize the important role that flushing continues to play, the FDA recently reminded consumers of the dangers of improperly disposing of certain medications by issuing a safety alert for fentanyl transdermal patches, whose disposal should be via flushing.[8]

The LCA fails to take into account the fact that drugs differ from most other commodities. Drugs are ubiquitous throughout society. They are stored in countless different places.[9] Consumer behavior with respect to the life cycle of a drug is extremely complex.[5] And certain medications are among the most toxic of all chemicals available to consumers.[5]

Beyond the health and safety concerns, the article is misleading in how it articulates the impact of disposal options on the overall emission of API residues to the environment. A careful reading is required to appreciate that statements regarding the overall effectiveness of the three disposal options in reducing "API emissions" pertain only to the *comparative* emission reductions among the three disposal options. The stated reductions do not apply to *absolute* reductions in overall ambient environmental API levels. As one example, the following statement can be misinterpreted to mean that API emissions to the environment can be "eliminated" via drug take-back programs: "It is observed that implementation of take-back programs can eliminate API emissions…" In reality, there are no data from ANY type of drug disposal program that show to what extent ambient environmental emissions can be reduced. In the final analysis, the contribution to ambient levels by flushing is a complex function of numerous variables, including pharmacokinetics of the individual API and patient behavior (such as adherence and compliance).[5-7] For most unwanted medications, however, flushing would probably contribute negligibly to the ambient aquatic levels for the respective APIs, as excretion is the major source.[5, 6]

The LCA presented by Cook et al.[1] also makes several assumptions that are not supported by published data. One example pertains to transportation emissions. It is unknown how many consumers would make a dedicated trip to a drug collection site or event rather than incorporate the task into errands they would ordinarily make. After all, one of the motivations for pharmacies in hosting co-located drug collections is to attract business; note, however, that the pharmacy operation itself is never involved in the collection process. Furthermore, not all options for take-back programs involve consumer travel. The State of Maine, for example, has pioneered a mail-back program.[10] Another example pertains to the statistics cited by most drug-collection events regarding the quantities of drugs collected (such as the unsubstantiated estimate of 200 million pounds provided in cited reference 20 [note: URL is incorrect]). These cited quantities rarely ever pertain to the mass of the actual APIs. Such data invariably include packaging and inert ingredients; the relative mass of the API is often minor. The cited quantities of leftover drugs used in assessing API reductions by various disposal options therefore may be wildly high.

Finally, it is important that the issue of unwanted drugs not become fixated on disposal. In the interest of sustainability and stewardship, it is also critical to make progress in redesigning the complex system surrounding the practices of medication prescribing and dispensing - with the

ultimate objective of minimizing the incidence of drug waste at the outset. Reducing the quantities of drugs that go unused (and reducing the hazards posed by used drug delivery devices) is more efficient with regard to both minimizing environmental impact as well as protecting human health and safety.[5, 7]

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