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# Communicating risk in the face of data gaps: toxic metals in tampons

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A recent correspondence<sup>1</sup> about our manuscript, *Tampons as a source of exposure to metal(loid)s*,<sup>2</sup> highlights the importance of data for complete risk assessment and public health communication when data gaps exist. Our study, which measured the concentration of 16 metals in tampons, detected the toxic metals lead (Pb), arsenic (As), and cadmium (Cd). Our study was the first of its kind, and we found the ubiquitous presence of most of the metals we tested for in our tampon samples. We concluded that tampon use is a potential source of exposure to metals for people who menstruate, and highlighted the need for future studies to assess the

30 bioaccessibility of these metals in tampons and their potential impacts on health.<sup>2</sup> None of the  
31 metals we measured was included in the ingredients packaging list of any of the tampons we  
32 tested. We shared our findings in a press release to inform the public, and, to avoid causing  
33 unnecessary alarm, emphasized the need for further research to fully characterize the potential  
34 exposure and health implications of metals in tampons.

35

36 In response to our study findings, the United States Food and Drug Administration (FDA), which  
37 regulates tampons as medical devices,<sup>3</sup> announced that it has “commissioned an independent  
38 literature review and initiated an internal bench laboratory study to evaluate metals in tampons.”<sup>4</sup>  
39 The goal of these scientific assessments is to “enable the FDA to complete a risk assessment of  
40 metals contained in tampons, based on a worst-case scenario of metal exposure.”<sup>4</sup> We support the  
41 FDA’s decision; further research is needed to determine the bioaccessibility of metals in tampons  
42 and vaginal absorption of metals, both locally and systemically, as these data gaps limit a fully-  
43 informed hazard and risk assessment of toxic metals contained in tampons.

44

45 In addition to this action by the FDA, our study and press communication has resulted in a  
46 fruitful partnership with the International Organization for Standardization (ISO), which is  
47 currently working to establish global safety standards for menstrual products. The ISO notes:  
48 “The lack of harmonized global standards for the safety and quality of menstrual products is  
49 contrasted with the stringent regulations for other products used on or inside the body, such as  
50 condoms and wound dressings.”<sup>5</sup> This partnership is another opportunity to ensure the safety and  
51 proper regulation of menstrual products.

52

53 In the correspondence,<sup>1</sup> Öberg has raised two main criticisms regarding our study and press  
54 communication: (1) the lack of provision of “relevant comparisons to current exposure levels and  
55 health-based reference values,” and (2) that the press release<sup>6</sup> by the University of California  
56 Berkeley (UC Berkeley) appeared “more focused on attracting attention than on ensuring  
57 accuracy”.<sup>1</sup> Öberg provides several examples to compare our findings to current exposure levels  
58 and health-based reference values,<sup>1</sup> and avers that “...the results suggest a negligible level of  
59 exposure of toxic metals from tampons” and “As and Pb are public health concerns, but given the

60 presented evidence, As and Pb in tampons are not.”<sup>1</sup> We respectfully disagree with this  
61 conclusion, noting that additional exposure data is needed to conduct a full health risk evaluation  
62 of metal exposure through tampons, which the FDA has committed to addressing.<sup>4</sup>

63  
64 Öberg estimates that vaginal exposure to Pb from the use of a single 1 g tampon (1 g <= 1 light  
65 absorbency tampon, the lowest absorbency on the market in the United States) provides relatively  
66 little exposure (120 ng) compared to daily oral ingestion of dietary Pb in a 60 kg woman (30,000  
67 ng).<sup>1</sup> This is a misleading comparison for four key reasons. (1) Light absorbency tampons are not  
68 commonly used;<sup>7</sup> regular (mass = 2 g), super (mass = 2.8 g), and super plus (mass = 3.3 g) are far  
69 more common. (2) Menstruators who use tampons typically use 3-4 a day,<sup>7</sup> ranging from 2 to as  
70 high as 18, depending on bleeding severity.<sup>8</sup> (3) No safe level of Pb exposure exists<sup>9</sup> no matter the  
71 route of exposure. (4) Chemical absorption has been shown to be more efficient via the vaginal  
72 route compared to the oral route of exposure.<sup>10</sup> In particular, unlike the oral exposure route,  
73 chemicals absorbed vaginally bypass first-pass metabolism by the liver and directly enter systemic  
74 circulation.<sup>10</sup> In light of the data gap regarding vaginal absorption of Pb with tampon use, Öberg’s  
75 conclusion of negligible risk based on exposure to a single light tampon is scientifically  
76 unsupported. While the exact exposure level of Pb from tampons or its absorption is currently  
77 unknown, given the use patterns described above and the high permeability of the vaginal  
78 epithelium, we expect it to be substantially higher than 120 ng.

79  
80 Öberg also asserts that exposure of 120 ng of Pb from a tampon would be roughly equivalent to  
81 the same amount of Pb lost through excretion of blood that is absorbed by a tampon, and thus that  
82 there is likely no net increase in Pb exposure.<sup>1</sup> This conclusion incorrectly assumes that the  
83 composition of human blood is the same as menstrual effluent.<sup>11</sup> It also overlooks the possibility  
84 that vaginal retention of a tampon saturated with menstrual effluent containing Pb and other  
85 metals for several hours could lead to some vaginal reabsorption of the metals.

86  
87 Importantly, Öberg’s exposure estimates lack crucial data on the actual bioaccessibility and  
88 absorption of metals in tampons, both locally and systemically. We contend that without this  
89 information, there is insufficient evidence to conclude that tampon-related metal exposure is

90 negligible.<sup>1</sup> This is why we did not make a conclusion about risk in our scientific paper or press  
91 release, instead stating that “tampon use is a *potential* source of metal exposure” (emphasis  
92 added).<sup>2</sup> We are currently conducting additional experiments to better characterize the extent to  
93 which metals leach from tampons, and the FDA is also investing resources in this important  
94 scientific work to “measure the amount of metals that come out of tampons under conditions that  
95 more closely mimic normal use.”<sup>4</sup> Further work is needed to characterize vaginal metal  
96 absorption.

97

98 Finally, Öberg argues that the UC Berkeley press release<sup>6</sup> is misleading and “raises alarms”,  
99 citing three quotes as evidence,<sup>1</sup> one of which is taken out of context to support this claim. Öberg  
100 writes: “...the press release quotes the senior author, stating that the study ‘clearly shows that...  
101 women might be at higher risk for exposure using these products.’”<sup>1</sup> However, the full quote in  
102 the press release states: “Although toxic metals are ubiquitous and we are exposed to low levels at  
103 any given time, our study clearly shows that metals are also present in menstrual products, and  
104 that women might be at higher risk for exposure using these products.”<sup>6</sup> The text Öberg omitted  
105 from the press release clarifies that low-level toxic metal exposure is common and clarifies that  
106 what our study clearly showed is that metals are present in menstrual products. The UC Berkeley  
107 press release also provides important context and makes clear our current lack of knowledge  
108 about the potential health risks associated with the presence of metals in tampons: “For the  
109 moment, it’s unclear if the metals detected by this study are contributing to any negative health  
110 effects.”<sup>6</sup>

111

112 In summary, we agree with the importance of accurate public health communication, including  
113 highlighting the scientific uncertainties related to studies that preclude clear determinations of  
114 health risk. However, without data on bioaccessibility and vaginal absorption of contaminants in  
115 tampons, we aver that Öberg’s effort to dismiss concerns about toxic metals in tampons is  
116 premature and unjustified. Our results indicate that tampon use may be a *potential* pathway of  
117 widespread population exposures to toxic metals and makes clear the urgent need for further  
118 research on the potential health implications of our findings.

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122

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