

Nickel and cobalt release from earrings and piercing jewellery – analytical results of a German survey in 2014

Wolfgang Uter¹  and Jörg Wolter²

¹Department of Medical Informatics, Biometry and Epidemiology, University of Erlangen/Nürnberg, 91054 Erlangen, Germany and ²State Office for Agriculture, Food Safety and Fisheries Mecklenburg-Vorpommern, 18059 Rostock, Germany

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Summary

Background. Nickel and cobalt are important metal allergens, and more knowledge on the levels of exposure to these from everyday contacts is needed.

Objectives. To report the results of a repeat routine surveillance scheme in the Federal Republic of Germany on the release of nickel and cobalt.

Methods. Fifteen laboratories assessed earrings and piercing jewellery items from 12 of the states in 2014, complying with EN 1811:2011 + AC:2012 and using atomic absorption spectrometry, inductively coupled plasma mass spectrometry and inductively coupled plasma optical emission spectrometry for quantification. Kaplan–Meier analysis for left-censored data was employed to account for measurements below the limit of quantification.

Results. Nickel release exceeded $0.35 \mu\text{g}/\text{cm}^2$ per week in 26 of 160 piercing posts (16.2%), and $0.88 \mu\text{g}/\text{cm}^2$ per week in 2.0–5.9% of other parts, that is, the current respective 'pass' thresholds, with no change from the previous 2008 survey. The level of cobalt release was lower than that of nickel release, and also significantly lower than in the previous survey.

Conclusions. The finding of the highest level of nickel release from piercing posts, with their deliberately lower threshold of acceptability, is worrying, as is the largely unchanged overall level of nickel release. A regulation on cobalt release is currently lacking; risk assessment and management based on dose-elicitation data are needed.

Key words: cobalt; exposure analysis; jewellery; nickel.

Nickel is the most common allergen according to most data on contact allergens, for example recent data from the European Surveillance System on Contact Allergies network (1). Efforts to regulate, that is, limit exposure of

the general population to nickel, have been reviewed (2, 3). One of the most recent advances has been the revision of EN 1811:2011, which became legally binding in Germany in April 2013. This revision concerned, among other aspects, a 'tolerance factor' applied to measurements of nickel release, which was previously 0.1. This meant that measurements of nickel release had been multiplied by this factor before acceptability of the item was determined against the limits of 0.2 and $0.5 \mu\text{g}/\text{cm}^2$ per week for piercing posts and all other metallic items that come into prolonged contact with the skin, respectively. In effect, the actual release was still acceptable even if it was 10 times higher, that is, 2 and $5 \mu\text{g}/\text{cm}^2$ per week. This has been criticized for undermining the efforts to limit nickel exposure of the population via consumer items (4). More

Correspondence: Professor Dr. med. Wolfgang Uter, Department of Medical Informatics, Biometry and Epidemiology, University of Erlangen/Nürnberg, Waldstr. 4-6, DE-91054 Erlangen, Germany. Tel: +49 9131 8522720; Fax: +49 9131 8522721. Email: wolfgang.uter@fau.de

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recently, a level of release between 0.11 and 0.35 $\mu\text{g}/\text{cm}^2$ per week from post assemblies, which had been previously defined as 'inconclusive', is currently accepted, and the item will pass the compliance check (3). A previous survey of piercing jewellery and earrings in Germany, performed in 2008, had indeed identified a notable proportion of items exceeding the release limits (4).

Although not as common as nickel allergy, cobalt contact allergy is found in approximately 5–7% of patch tested patients (1). At the level of the general population, sensitization prevalence has been estimated to be 1.1% in males and 3.0% in females (5) on the basis of a large ($n = 3119$) sample in five European countries. Some specific exposures to cobalt are found in industrial settings, but the vast majority of cobalt sensitization, especially in young females who are often, but not always, also sensitized to nickel, is largely unexplained.

Such unclear clinical relevance is also attributable to the fact that adequate exposure data have, until recently, been lacking. The broad availability of a cobalt spot test (6), which allows identification of cobalt release by metallic items similarly to the identification of nickel release with the dimethylglyoxime (DMG) spot test (7), has already increased our knowledge of potential exposure sources. However, neither spot tests is highly sensitive; for example, the sensitivity of the DMG test against a release threshold of 0.5 $\mu\text{g}/\text{cm}^2$ per week verified by X-ray fluorescence spectroscopy has been found to be only 59% (8). For the cobalt spot test, the detection limit has been estimated to be 8.3 ppm (6). Therefore, quantitative determination of nickel release under the conditions of EN 1811:2011 is necessary to achieve a more precise, fully quantitative impression of the amount of exposure. This also holds true for cobalt, although, hitherto, no threshold criterion has been established for the regulation of cobalt exposure.

The present article presents the results of a German survey performed in 2014 on nickel release, which is a follow-up of the 2008 survey. The majority of laboratories also analysed cobalt release under the same conditions as laid down in EN 1811:2011. The distribution of measured release values will be described for both nickel and cobalt, both overall and stratified for different parts of the jewellery items, that is, piercing posts, clasps and decorative parts, and will be compared with the values found in the 2008 survey (4, 9).

Methods

Background information on the survey is available in the general publication on the 'Bundesüberwachungsplan' (10) in the German language. Briefly, different types

of fashion and piercing jewellery were sampled by the responsible authorities for surveillance of food and non-food products, and measured by the responsible investigation offices. In 12 of the 16 German federal states, earrings and piercing jewellery items were bought in a variety of shops. In the vast majority, these were obtained in retail shops ($n = 191$), drug stores ($n = 17$), hairdressing or beauty salons ($n = 4$), kiosks or bars ($n = 5$), wholesale dealers or importers ($n = 11$), and other shops ($n = 18$). For nine, the source was not documented. The origins of jewellery were, for approximately half of the jewellery items, China, including Tibet ($n = 125$), other Asian countries ($n = 23$), EU countries ($n = 9$), and Switzerland ($n = 2$); for 98 items, the origin was unclear or not documented. Pricing information was not available in this survey.

For preparation, the jewellery items were (mostly) dismantled. Surfaces of the parts not coming into contact with the skin were masked with lacquer. Thereafter, the product samples (parts) were immersed in artificial sweat, which consisted of deionized and aerated water containing 0.5% sodium chloride, 0.1% lactic acid, and 0.1% urea. The pH was adjusted to 6.5 with sodium hydroxide. The flasks were left in an oven at 30°C for 1 week for metal extraction, all in accordance with EN 1811:2011 + AC:2012. The laboratories listed in Table 1 performed these analyses; sometimes samples from several states were analysed in one laboratory, and sometimes more than one laboratory analysed samples from one state. The analytical methods used in the respective laboratories are also shown. The resulting amount of metal was divided by the exposed surface area to determine the nickel and cobalt release rate ($\mu\text{g}/\text{cm}^2$ per week). The exposed surface area of each single part was calculated manually with Vernier callipers or micrometers. The limit of quantification (LOQ) and the limit of detection were both measured in micrograms per litre of release solution. Although the LOQ per volume unit of sample liquid was fixed in one laboratory, owing to varying (i) surface areas of the objects and (ii) volumes of the release solution (artificial sweat), the relevant effective LOQ in terms of $\mu\text{g}/\text{cm}^2$ per week varied between samples. It should be noted that the measured values for both metals were used 'as is', i.e., without applying any 'correction factor' in the present analysis.

For the analysis, which addressed the release of metals from different parts of the jewellery item, the majority of the 258 jewellery items were dismantled into (in one case) up to nine single parts, 106 were analysed in one piece, or only one part of the jewellery item was considered (e.g. the piercing post of a non-metal earring). The median number of parts per jewellery items was two, and

Table 1. Analytical methods used by the participating laboratories

State	Laboratory	Method	N (items)	N (samples)
Baden-Württemberg	Fellbach	ICP-MS	11	33
Berlin-Brandenburg	Berlin	ICP-OES	39	72
Hessen	Wiesbaden	AAS	32	82
Mecklenburg-Vorpommern	Rostock	ICP-MS	49	152
Nordrhein-Westfalen	Detmold	ICP-OES	18	22
Nordrhein-Westfalen	Krefeld	ICP-MS	31	60
Nordrhein-Westfalen	Bochum	ICP-OES	13	28
Nordrhein-Westfalen	Aachen	AAS	30	48
Rheinland-Pfalz	Koblenz	AAS	13	15
Sachsen	Dresden	ICP-OES	6	11
Schleswig-Holstein	Neumünster	AAS	4	7
Thüringen	Langensalza	ICP-MS	10	32

AAS, atomic absorption spectrometry; ICP-MS, inductively coupled plasma mass spectrometry; ICP-OES, inductively coupled plasma optical emission spectrometry.

One laboratory contributing one sample and one item is not shown (Erlangen).

the third quartile was three. The numbers of single parts, categorized into posts, clasps, and decorative parts, or whole items, are shown in Table 2, along with some basic analytical results, stratified for nickel and cobalt release. Whereas the analysis of nickel release was mandatory in the official survey, additional analyses addressing cobalt and chromium were performed by only a subset of laboratories. Altogether, parts of 257 jewellery items were available for nickel analysis, and parts of 159 jewellery items were available for cobalt analysis; for further details, including a breakdown of the different parts of these items, see Table 2.

The statistical methods used in the present analysis have been extensively described in a previous publication (9). Briefly, the empirical distribution of the metal measurements was derived with Kaplan–Meier analysis for left-censored data. The Kaplan–Meier approach yields an estimate of the empirical distribution function, and hence a curve that visualizes the estimated probability that a nickel and cobalt release value, respectively, is smaller than or equal to a certain value. Censored measurements are indicated by short vertical bars intersecting the curve. The curve can thus be regarded as a special variant of an empirical distribution function with adequate representation of values below the LOQ (11). Data management and analysis were performed with the statistical software R [version 3.4.0 (12), <http://www.R-project.org/>] and the R add-on package NADA (version 1.6-1).

Results

Basic results in terms of the number of samples (different categories of parts of jewellery items), and the number and proportion with measurements below the LOQ and above

Table 2. Characteristics of the samples and nickel and cobalt release. It should be noted that no restrictions exist concerning cobalt release, so the proportions of samples above the same thresholds as exist for nickel have a hypothetical significance. ‘% with measurements’ denotes the proportion of objects for which nickel release could actually be measured; in the remainder, release was below the limit of quantification

	Nickel (n = 257)	Cobalt (n = 159)
No. of piercing posts	160	99
No. (%) of piercing posts with measurements	89 (55.6)	54 (54.5)
No. (%) of piercing posts releasing > 0.2 ^a	36 (22.5)	7 (7.1)
No. (%) of piercing posts releasing > 0.35 ^a	26 (16.2)	3 (3)
No. of clasp parts	101	59
No. (%) of clasp parts with measurements	55 (54.5)	38 (64.4)
No. (%) of clasp parts releasing > 0.5 ^a	6 (5.9)	1 (1.7)
No. (%) of clasp parts releasing > 0.88 ^a	6 (5.9)	0 (0)
No. of decorative parts	251	158
No. (%) of decorative parts with measurements	137 (54.6)	93 (58.9)
No. (%) of decorative parts releasing > 0.5 ^a	15 (6)	0 (0)
No. (%) of decorative parts releasing > 0.88 ^a	10 (4)	0 (0)
No. of whole items	51	53
No. (%) of whole items with measurements	8 (15.7)	4 (7.5)
No. (%) of whole items releasing > 0.5 ^a	3 (5.9)	2 (3.8)
No. (%) of whole items releasing > 0.88 ^a	1 (2)	2 (3.8)

^aµg/cm² per week.

certain threshold values, are shown in Table 2, similar to the results presentation in a previous publication (4).

The main emphasis is, however, on the optimum use of the full scope of measurement results, including both actually measured values and censored values, with the individual LOQ of the respective analysis as a maximum estimate of the value expected in that sample. Results concerning nickel are shown in the next section,

including a comparison with results from the 2008 survey. Results concerning cobalt are described in the subsequent section. Finally, the joint distribution of nickel and cobalt measurements is shown in an identical fashion as in the 2008 analysis [Fig. 3 in (9)].

Nickel

Some basic characteristics of nickel measurements have already been shown in Table 2. The distribution of nickel release measurements, stratified for the three types of parts considered, and additionally including whole parts that were not dismantled, is shown in Fig. 1a. Quite amazingly, posts, with their lower threshold limit of $0.2 \mu\text{g}/\text{cm}^2$ per week, had higher measurements, which is a statistically significant finding in a regression analysis with the four types of parts/whole parts as an explanatory factor, and with clasps as a reference ($p = 0.004$).

Next, a comparison of overall nickel release from the 2008 and the 2014 samples is shown in Fig. 1b. As the composition of the two samples in terms of included parts may have differed, and nickel release has been found to differ between the parts, a regression analysis was performed with year as the factor of interest and part as a covariate. This adjusted analysis showed no significant difference in overall nickel release between the two surveys ($p = 0.93$).

Cobalt

The distribution of cobalt release values was determined in a subset of the entire sample (it is, unlike nickel, not a mandatory item of the surveillance scheme), that is, in 159 jewellery items dismantled, or not, into 369 different parts, corresponding to 64.7% of all parts. The distribution in terms of the Kaplan–Meier estimate is shown in Fig. 2a. The pattern was similar to that observed with nickel, although the difference – albeit significant at $p = 0.018$ – between posts and remaining parts was not as marked.

The cobalt release values were analysed in the same fashion as in the present publication following the 2008 survey (9). For easier comparison, the overall values, that is, those obtained after aggregation of all different parts, were graphically compared (Fig. 2b). Another regression analysis was performed with year as the factor of interest and part as a covariate. This adjusted analysis showed significantly lower amounts of overall cobalt release in the current survey than in the previous survey ($p < 0.001$).

Nickel and cobalt

The bivariate distribution of cobalt and nickel release was assessed in the 2008 sample (9). A verification of

the previous observation was considered to be of interest, and is shown in Fig. 3 as a scatter plot, in which the black dots represent measurements on the same part where both cobalt and nickel could be measured; that is, both measurements were higher than the LOQ. The grey squares and triangles represent measurements in which only nickel and only cobalt, respectively, were actually measured, the other metal being below the LOQ. Overall, the correlation was found to be just weakly positive (Kendall's tau for censored data = 0.186), although significantly different from zero ($p < 0.001$).

In the majority ($n = 334$, 91%) of samples (different parts) in which nickel release was found to be 'acceptable' against the 'adjusted' criteria of 0.35 and $0.88 \mu\text{g}/\text{cm}^2$ per week, respectively, and cobalt release had been measured on the same object, cobalt release was significantly lower than that from the non-compliant items ($n = 33$, 9%) (Fig. 3b). Thereby, the observed positive correlation between nickel and cobalt release was confirmed.

Discussion

The repetition of a survey concerning the release of nickel (and cobalt) from earrings and piercing jewellery 6 years after the previous survey allows a comparison of results. In both surveys, no 'adjustment' for the 'tolerance' factors included in the versions of EN 1811, namely, EN 1811:1998 valid at the time of the previous survey, and EN 1811:2011 valid at the time of the current survey, was used, which enables a direct comparison.

A non-negligible proportion of jewellery items still releases nickel, and also cobalt. As one main finding, the amount of overall nickel release did not change. This lack of difference was confirmed by a statistical test that was adjusted for different compositions of the samples, most importantly concerning the proportion of piercing posts, with their lower limit of nickel release. It is quite worrying that the parts releasing most nickel were exactly those, namely piercing posts, that should release the least nickel.

In contrast to nickel, the amount of cobalt release decreased considerably in the 6 years between the surveys, although no regulation is in force that could have prompted such a change. Evidently, this reduction is very welcome from the perspective of preventing sensitization and elicitation by cobalt leached from such commonly used consumer jewellery. Concerning the question of which levels of cobalt exposure could be regarded as acceptable in terms of most likely preventing induction of sensitization, and in terms of protecting the majority of sensitized persons from elicitation, a recent review has identified five studies finding doses eliciting allergy in 10% of cobalt-sensitive individuals (ED_{10}) of 0.0663,

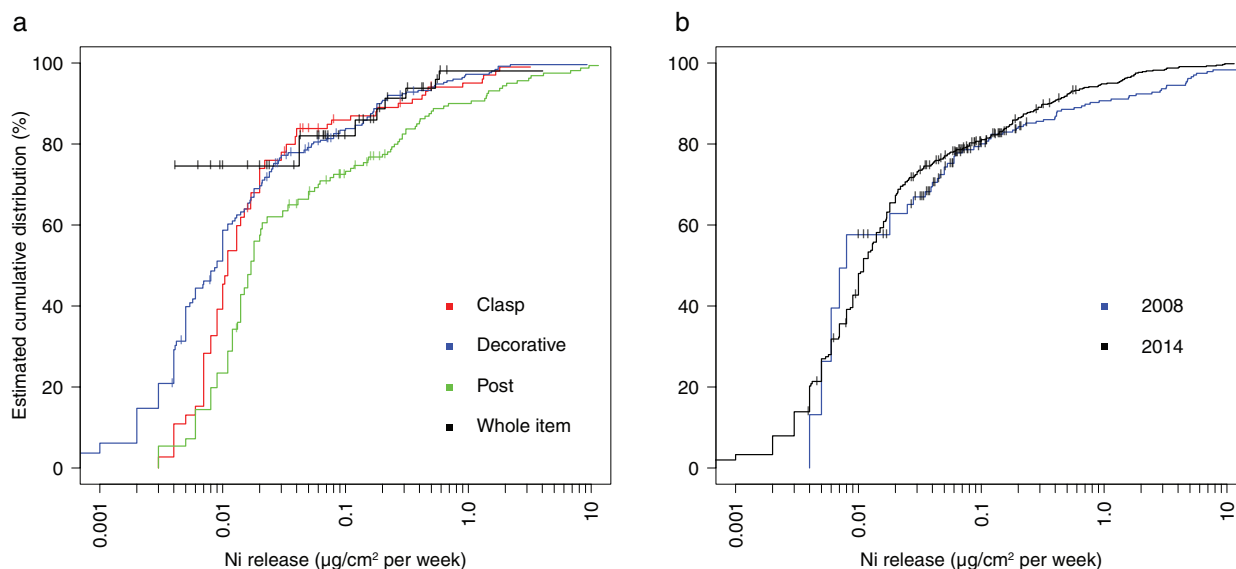


Fig. 1. (a) Distribution of measurements of nickel (Ni) release after immersion according to EN 1811:2011, stratified for four different parts. The curve represents the estimated cumulative distribution function of the measurements as obtained from Kaplan–Meier analysis. Left-censored measurements (i.e. with a missing measurement, which has been replaced with the limit of quantification of the respective sample, in 49.3% of all samples) are indicated by short vertical bars. For further explanation, see text. (b) Distribution of measurements of nickel release after immersion according to EN 1811:2011, comparing the overall results of the present survey (black line) with those of the previous survey (2008, blue line). The difference in distribution, adjusted for different parts, is not significant ($p = 0.93$).

0.441, 0.571, 0.647 and $1.95 \mu\text{g}/\text{cm}^2$, respectively (13). On comparison of these ED_{10} estimates with the cobalt release observed here, it is evident that a (varying) proportion of jewellery will release cobalt above these values.

Exposure to earrings and piercing jewellery is a prototypic type of ‘prolonged exposure’; in this context, the approach of EN 1811 of measuring long-term release, over 1 week, under simulated use conditions regarding temperature, electrolytes and other factors can probably still be regarded as valid. However, in addition to this well-recognized pattern of exposure, repetitive short-term contact with metallic objects, and the metal release and skin deposition associated with it, have been addressed by the European Chemicals Agency in terms of considering ‘potentially more than 10 min on three or more occasions within 2 weeks’ or ‘30 min on one or more occasions within 2 weeks’ as the minimum requirement for ‘prolonged contact’ (14). Since then, the wide spectrum of objects for which such a pattern of repetitive, shorter contact can be found has gained increasing attention (15, 16).

The previously observed slightly weaker correlation between nickel and cobalt release [Kendall’s tau for censored data = 0.099 (9)] is quite similar to the currently observed weak correlation; the slight difference may be attributable to the overall lower amount of cobalt release in the present sample. Generally, discussion with

material scientists from the fashion industry suggests that both metals are more likely to be used alone than as a combination.

Both nickel and cobalt release have been examined in several studies involving laboratory analysis, such as the present study. For instance, a study found release of nickel from 79 of 96 US samples (0.01 – $598 \mu\text{g}/\text{cm}^2$ per week) and release of cobalt from 35 of these samples (0.02 – $0.5 \mu\text{g}/\text{cm}^2$ per week) (17); as the distribution of measurement values beyond the range given was not reported, a comparison with the present results is difficult. It is of note that the proportion of German samples above the LOQ was considerably lower regarding nickel, that is, $\approx 55\%$ (see Table 2), than in the US samples (79/96; 82%), which could be interpreted as a reflection of longstanding nickel regulation in Europe. However, concerning cobalt, with $\approx 60\%$ of samples above the LOQ, as compared with 35 of 96 (36%) of the US samples, a higher proportion of cobalt release was found in Germany. Possibly, differences in analytical methodology make an exact comparison uncertain; however, the pattern is interesting.

Alternatively, the spot tests available for both metals can be, and have been, used for nickel (7, 8) and for cobalt (6, 18), respectively. Although not as sensitive as chemical analysis, the spot tests are (i) non-destructive and (ii) enable quick screening of metallic objects, for example

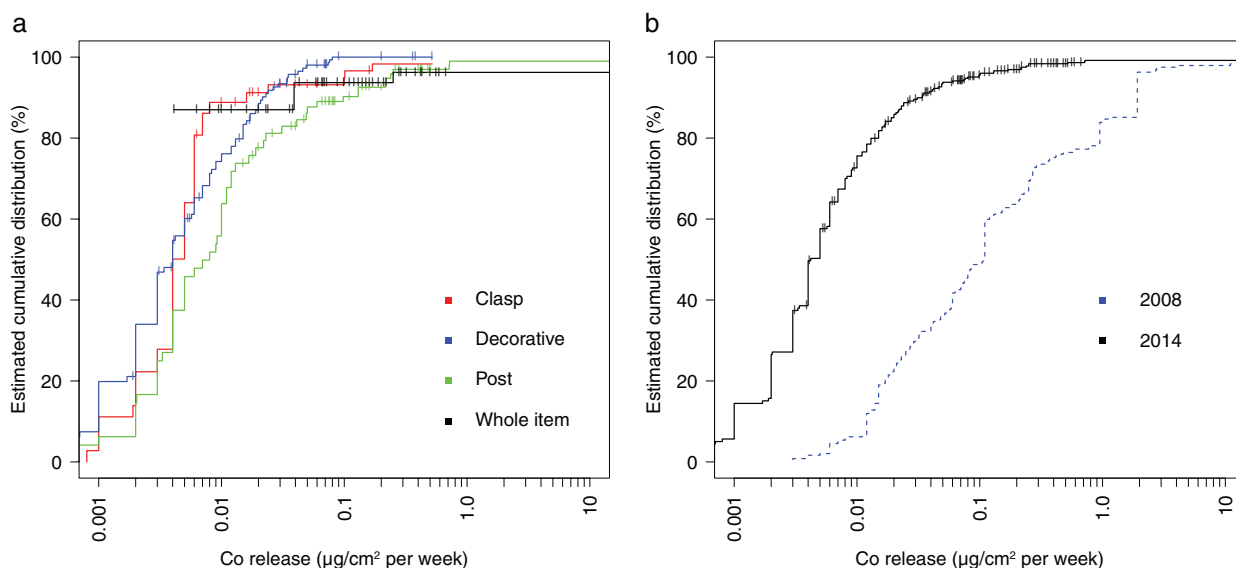


Fig. 2. (a) Distribution of measurements of cobalt (Co) release after immersion according to EN 1811:2011, stratified for four different parts. Left-censored measurements (i.e. with a missing measurement, which has been replaced with the limit of quantification of the respective sample, in 66.8% of all samples) are indicated by short vertical bars. For further explanation, see text. (b) Distribution of measurements of cobalt release after immersion according to EN 1811:2011, comparing the overall results of the present survey (solid line) with those of the previous survey (2008, dashed line). The difference in distribution, adjusted for different parts, is significant ($p < 0.001$).

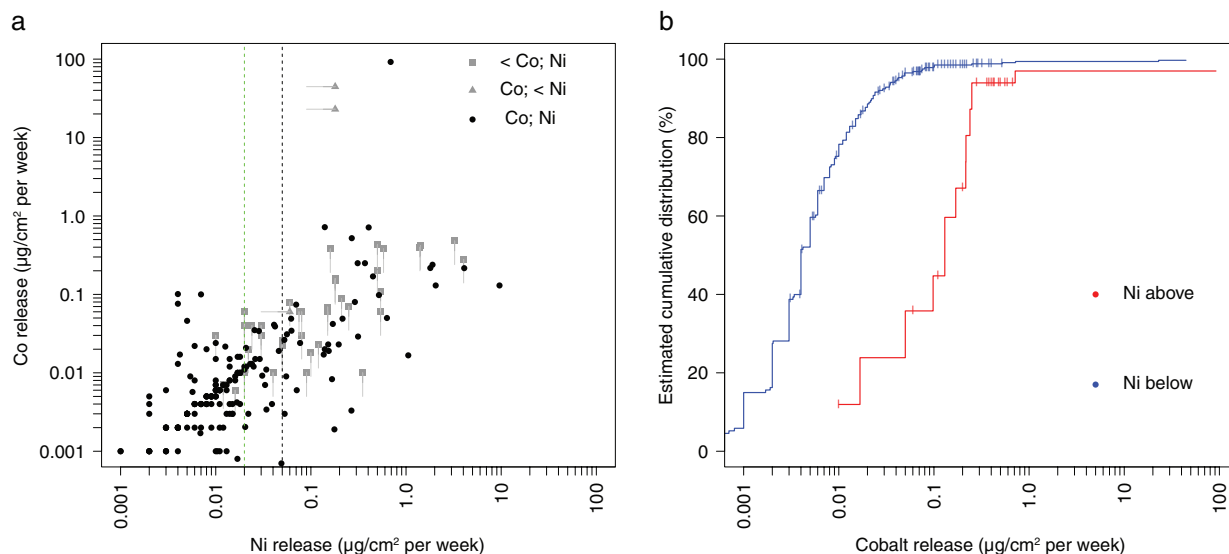


Fig. 3. (a) Scatterplot of the paired measurements of nickel (Ni) (x-axis) and cobalt (Co) (y-axis) release. Black dots indicate measurements with actually observed values for both cobalt and nickel, and grey symbols indicate those measurements in which either cobalt or nickel or both were censored (the '<' symbol indicates censored values). Information contributed by these latter (partly censored) pairs of measurements must be interpreted with caution; see text. (b) Cobalt release (overall, i.e. irrespective of part) in those samples that release $\geq 0.2 \mu\text{g}/\text{cm}^2$ per week in the case of posts, and $\geq 0.5 \mu\text{g}/\text{cm}^2$ per week in the case of all remaining samples (red), and those parts that fall below these limits concerning nickel release (blue); significantly higher cobalt release in samples with nickel release of ≥ 0.2 and $\geq 0.5 \mu\text{g}/\text{cm}^2$ per week ($p < 0.001$).

by patients found to be allergic to one or both metals. For instance, in a sample of 557 earrings bought in China and Thailand, only four released cobalt (19). This observation supports the notion that higher cobalt content and release may be more likely to be found in more expensive jewellery, owing to the higher cost of cobalt than of nickel (11.60 US dollars/kg for nickel versus 59.25 US dollars/kg for cobalt, according to ad hoc Internet research, performed on 16 October 2017). In a Korean sample, nickel release was detected in 47.8% of 471 spot-tested jewellery items, whereas cobalt release was found in 6.2% of items, that is, in a slightly higher proportion than in the Chinese/Thai sample. However, a much higher proportion of cobalt-releasing jewellery items was found in another Thai study (20) by spot-testing, namely 37.4% of 551 used costume jewellery items obtained from volunteers; the proportion of nickel-releasing items was quite similar, at 39.2%. Therefore, the sampling methodology may have a large impact on the results if one country is considered.

Conclusion

Continual surveillance of consumer objects such as is offered by the German scheme enables the identification of shortcomings in compliance with consumer protection regulations. In the present case, the proportion of piercing posts with excessive nickel release calls for even more responsible manufacturing standards. The role of cobalt, a much more expensive component of jewellery alloys than nickel, should be examined further. In particular,

further analysis of the distribution of individual elicitation thresholds in cobalt-sensitized persons, possibly related to outcomes of use tests with objects with defined release, seems warranted to achieve proper risk assessment and risk management actions concerning cobalt. Moreover, the correlation of quantitative, analytical results, such as those presented here, and spot testing for cobalt should be studied further. These results should then be related to above-mentioned critical elicitation thresholds.

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