STRATEGY TO EVALUATE THE IMPACT OF FORMALDEHYDE IN ANATOMIC PATHOLOGY LABORATORY
PART II: SHORT- VERSUS LONG-TERM EXPOSURE

SUMMARY: Formaldehyde (FA) is a hazardous chemical, highly used in the anatomical pathology laboratories. The adverse health effects related to FA occupational exposure are generally related to long-term exposure, however the short-term exposure to peak concentrations are equally of high concern. The occupational monitoring commonly uses the 8h-Time Weight Average (TWA) metric to assess the exposure, but for those chemicals with acute effects, also the 15min short-term exposure is strongly recommended. In this study, the occupational monitoring was carried out in an anatomical pathology laboratory with an in-continuous, instantaneous, and direct reading instrument for 65 work shifts (WS). In none of these, the FA European Union (EU) TWA occupational limit (620 μg/m³) was exceeded. Differently, in 40 WS the EU Short Term Exposure Limit (STEL) (740 μg/m³) was exceeded, even several times a WS. In sight of this, the 8h-TWA metric only could give poor information of the exposure scenario, involving peak emissions, then a 15min peak exposure assessment, via in continuous monitoring, could help managing the risk. In addition, using the inference equation, an Action Value (AV) of the 8h-TWA above which the 15min measurements are strongly recommended, equal to 23.1 μg/m³, is suggested for FA.

Key words: formaldehyde, occupational monitoring, occupational exposure

INTRODUCTION

Formaldehyde (FA, CAS No. 50-00-0), recognized as the gold standard fixative (Hopwood, 1969) for is availability and cheapness, allows a long-term storage and preserves lipids. Since 1892, Jean Auguste Trillat observed its ability to harden soft tissues and trigger coagulation (Musiał et al., 2016). Formalin, which is a water solution of FA, allows one to rapidly obtain as much histopathological information as possible from a fixed tissue. Moreover, the alternative fixatives studied to date, don’t own the FA efficacy on preserving the same broad range of tissue samples (Moelans et al., 2011). Thus, that is the reason why the 81% of United State (US) histology laboratories and in close to two-thirds in the rest of the world, FA is used as the standard fixative for routine work (Buesa, 2007).

In anatomical-pathology sector, FA leads to different occupational health risk problems for all employees, considering that a laboratory can handle until 20 tons per year of this chemical. In 2017, Scarselli et al. (2017) in a study to estimate the Italian occupational exposure to FA, reported...
that in the healthcare sector were recorded the highest average levels of airborne FA exposure, particularly among medical doctors and laboratory technicians. The acute health effects due to FA exposure reported by students, teachers, and laboratory personnel involve smell and sensory irritation of the nose, nasal cavity, pharynx, larynx, and eyes (Nielsen et al., 2017, Onyije & Avwioro, 2012, Vimercati et al., 2010, Flyholm & Menne, 1992). In addition to these short-term health effects, there is concern about long-term effects, including an increased risk of carcinogenicity. An analysis on the cause of death among pathologists in the United Kingdom from the 1950s until the late 1980s, performed by Harrington et al. (1991) highlighted how the excessive death rates due to suicide, and higher rates of brain tumours, hematopoietic and lymphatic malignancies, could be attributable to FA exposure. Concerning FA exposure risk, updates of the US National Cancer Institute (NCI) cohort confirmed that the relative cancerogenic risk was not increased with mean FA exposures below 1 ppm and peak exposures below 4 ppm (Beane et al., 2013).

Since 2013, new key studies have been published, and key cancer cohorts have been updated, confirming that FA is genotoxic, causing DNA adduct formation (Nielsen et al., 2017). Although FA is proven for nasopharyngeal cancer (IARC, 2006- FA, 2-butoxyethanol and 1-tertbutoxypropan-2-ol. IARC Monogr Eval Carcinog Risks Hum, 88: 1–478. PMID:17366697) (IARC, 2006) in 2022, the US Environmental Protection Agency (EPA) in an updated analysis reported that long-term FA exposures increase the risk of rare head and neck tumours (Rizzuto, 2014). Always in relation to chronic exposures, Yu et al. and Xu et al. revealed an association between FA exposure and increased risk of asthma in children (2020), and miscarriage in Chinese women (2017). Ghelli et al. (2022) evaluated the FA relationship with the formation of sister-chromatid exchanges (SCEs) in cultured peripheral blood lymphocytes on 57 pathologists and 48 controls, highlighting that the former, exposed to 55.2 μg/m³ of air-FA, showed a significantly higher SCEs frequency than controls, exposed, respectively, to 18.4 μg/m³.

To prevent workers' injuries and illness occupational hygiene use environmental monitoring and analytical methods to evaluate and detect the extent of worker exposure to potential health hazards. Those tools and their respective results can be used to demonstrate compliance of the workplace exposure with existing limits, regulations, and guidance values. In this perspective, since there are substantial differences among associations' guidelines concerning FA occupational exposure, it's critical to define a limit value that allows to improve workplace conditions, minimizing potential exposure (Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA)-Deutsche Gesetzlich Unfallversicherung (DGUV)); (American Chemistry Council (ACC), 2016).

Figure 1. Worldwide occupational limit values for formaldehyde. TWA 8h long term limit, STEL: 15min short term limit, Ceiling: Ceiling values, as concentration in air that should not be exceeded during any part of the working exposure
Slika 1. Svjetske profesionalne granične vrijednosti za formaldehid. TWA 8 h dugoročno ograničenje, STEL: 15 min kratkoročno ograničenje, strop: gornje vrijednosti, kao koncentracija u zraku koja se ne smije prekoračiti tijekom bilo kojeg dijela radnog izlaganja

In account, the disagreements in the adoption of an univocal limit value to assess FA exposure between the different councils, the US National Institute for Occupational Safety and Health (NIOSH) proposed a thirty minutes-Immediately Dangerous to Life or Health (30min-IDLH) of 20 ppm for FA (Prevention, 2014).
Traditionally, the arithmetic and geometric mean and standard deviation of an 8h-TWA are performed to assess exposure to a hazardous substance. Controlled studies in humans report that short-term exposure (i.e., less than 1 hour) to FA air concentrations below 2 ppm produces no toxicological effects on the eyes or on tissues in the upper respiratory tract (Golden, 2011, Paustenbach, et al., 1997). This finding has been extensively confirmed in studies with rats and monkeys, which show that even with long-term exposure, FA does not cause pathological lesions or changes in respiratory tract tissues at air concentrations below 3 ppm (Paustenbach, et al., 1997). Nevertheless, some Authors (Blair & Stewart, 1990, Kumagai & Matsunaga, 1995) considered that the 8h-TWA metric is dependent on the toxicological mechanism of the chemical studied. Moreover, high duration exposures produce an elevated dose rate at target tissues and organs, potentially altering metabolism, overloading protective and repair mechanisms and amplifying tissue responses. Because of these aspects, it has been hypothesized that short-term high exposure levels could play a role in aetiology of chronic occupational diseases, traditionally associated with exposures accumulated over a long time period (Viegas et al., 2013).

Considering FA-induced sensory irritation, there are essentially no meaningful differences between short-term and longer-term exposure (Shusterman et al., 2006). As concluded by National Academy of Sciences (NAS), “Formaldehyde irritation does not appear to follow Haber’s law (concentration [c] × exposure time [t] = response [k]) for extrapolating between short-term and long-term toxicity levels. Generally, concentrations that do not produce short-term sensory irritation also do not produce sensory irritation after repeated exposure.” (National Academy of Sciences (NAS), 2007) Also noted by NAS was that “The degree of sensory and irritant effects at lower exposure levels depends on concentration rather than duration (National Academy of Sciences (NAS), 2007).” This conclusion is based on test results derived from human chamber studies that show that once symptoms are produced at a certain concentration, they are not enhanced with additional exposure time. It should be emphasized that this phenomenon applies only to sensory irritation and not to tissue-damaging events such as cytotoxicity following exposure to higher concentrations.

Characterization of peak exposures in occupational hygiene is then a problem that has long eluded an empirical solution. In this perspective, an increased interest is grown around instantaneous, in-continuous, direct-reading FA monitors to simplify the sampling process and analytic operations, and to take into account of the short-term peak exposure. Several works concerning FA air monitoring in the anatomical pathology laboratories showed the consistency of portable/transportable direct-reading instruments, and their easily integration into an occupational hygiene plan to prevent significant exposure (Dugheri, et al., 2020, 2021, Hirst et al., 2011). These in-continuous systems are in any case complementary in the evaluation of occupational exposure, by comparison with limit values, to conventional monitoring and analysis methods, among which, the most accredited and validated is based on either active or passive sampling with cartridge loaded with 2,4-dinitrophenylhydrazine (DNPH) and related chromatographic analysis with liquid chromatography (LC) or gas chromatography (GC).

This article presents a study conducted in an anatomy pathology laboratory to assess the relevance of short-term exposure to FA. An in-continuous, instantaneous, and direct monitoring approach was carried out during n.65 Work Shifts (WS) to evaluate the FA concentrations, as 8h-TWA and 15min-STEL. The aim of the study is to show how an occupational environment with 8h-TWA values under the mandatory limit could equally face dangerous peak exposures. In sight of this, an Action Values (AV), as the 8h-TWA concentration above which a 15min short-term exposure assessment is recommended, was defined in order to guide the necessary future FA monitoring campaigns to understand the exposure scenarios.

**MATERIALS AND METHODS**

This study was carried for n.4 months between 2021 and 2022 in the anatomical pathology laboratory, at the General Hospital of Macerata (Macerata, Italy). Environmental air monitoring was
RESULTS AND DISCUSSION

Health effects resulting from occupational exposure to FA are associated, generally, to exposure data based on 8h-TWA (Ladeira et al., 2011). However, some Authors have found that the mortality rate from leukaemia (Hauptmann et al., 2004, 2009, Dreyfuss, 2010, Zhang et al., 2009) and nasopharyngeal cancer (Pinkerton et al., 2004) increased significantly not just with the number of years of activity, but also with peak exposure to FA. Thus, high peaks are of special concern, also because they can produce an elevated dose rate at target tissues and organs, potentially altering metabolism, overloading protective/repair mechanisms (Preller et al., 2004).

In this context, this study shows that no WS exceeded the EU 8h-TWA limit value, either the current limit value of 620 μg/m³ or the limit value in effect from 2024 of 370 μg/m³ (Table 1). Thus, concerning the occupational exposure assessment, these data could be sufficient to consider the workplace safe and the working activities in “compliance” with the mandatory regulations. However, in light of the possible contribution of 15min short-term exposures to high FA concentrations, data analysis shows that exceedance of the EU 15 min-STEL (740 μg/m³) - as the 15-min time- weighted average exposure that should not be exceeded at any time during a WS, even if the overall 8-h TWA is below the 8h-TWA limit value - was observed on 61.5% of the monitored WS. Considering that, according to the American Conference of Governmental Industrial Hygienists (ACGIH), workers should not be exposed more than four times per day to concentrations above the TLV-TWA up to the TLV-STEL, with an interval between these exposures of at least 60 minutes, in 14 WS (21%) exceedances of 740 μg/m³ even occurred several times within the same WS; such exceedances also often occur up to three times, with a frequency of less than one hour (7 WS, 10.5%). Moreover, taking into account the DFG’s proposed Ceiling value of 1200 μg/m³, its exceedance was observed in 30 WS (ranging from 1208 to 6508 μg/m³).
Table 1. Data analysis of the monitored working shifts

<table>
<thead>
<tr>
<th>Work Shift (WS)</th>
<th>number</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>65</td>
<td>100</td>
</tr>
<tr>
<td>&gt; 8h-TWA 620 μg/m3*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&gt; 8h-TWA 370 μg/m3**</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>&gt;15min-STEL 740 μg/m3***</td>
<td>40</td>
<td>61.5</td>
</tr>
</tbody>
</table>

*EU 8h-TWA since 2024, ** EU 8h-TWA valid from 2024, *** EU 15 min STEL value.

Then, the experimental 8h-TWA values, observed in the days where the FA concentration is upper than 740 μg/m3 at least one times during the WS (40, equal to 61.5% of the total), were used to calculate the 15min concentration using the inference equation (Hunsaker, 2016)

\[
\text{Concentration value}_{15\text{min}} = \left[\frac{480 \text{ min}}{15 \text{ minutes}}\right] \times \text{Concentration value}_{8h}
\]

The theoretical values showed a good accordance with the measured ones, with a variability that ranges from 11 to 22%. This suggest to analyze other studies, carried out in anatomical pathology labs and dissection rooms, to find how important could be the FA peak exposure in these environments (Table 2).

Table 2. Inferential analysis of the 8h-TWA value reported in literature

<table>
<thead>
<tr>
<th>Authors</th>
<th>Site</th>
<th>Sampling</th>
<th>TWA (mg/m³)</th>
<th>Inference value (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee et al.</td>
<td>anatomical pathology laboratory</td>
<td>8</td>
<td>0.3</td>
<td>9.6</td>
</tr>
<tr>
<td>Yahyaei et al.</td>
<td>anatomical pathology laboratory</td>
<td>8</td>
<td>0.4</td>
<td>12.5</td>
</tr>
<tr>
<td>Adamovic et al.</td>
<td>dissection room</td>
<td>8</td>
<td>0.6</td>
<td>18.0</td>
</tr>
<tr>
<td>Vimercati et al.</td>
<td>anatomical pathology laboratory</td>
<td>4.2</td>
<td>0.5</td>
<td>8.0</td>
</tr>
<tr>
<td>Zain et al.</td>
<td>anatomical pathology laboratory</td>
<td>8</td>
<td>0.5</td>
<td>15.4</td>
</tr>
<tr>
<td>Ochs et al.</td>
<td>dissection room</td>
<td>4</td>
<td>2.0</td>
<td>32.0</td>
</tr>
<tr>
<td></td>
<td>dissection room</td>
<td>2</td>
<td>4.6</td>
<td>37.4</td>
</tr>
</tbody>
</table>
Similar Studies, carried out in anatomical pathology laboratories, with 8h sampling and 8h-TWA observed values less than 0.620 mg/m³, show that the inferred values on 15min (from 8.0 to 18.0 mg/m³) far outweigh the EU STEL limit.

In addition, Ochs et al. reported a 4h-TWA value equal to 2.0 mg/m³, that corresponds to a STEL value of 32 mg/m³, that can get dangerously close to the IDLH limit. In sight of this, and in agreement with other studies (Viegas et al., 2013, Meijster et al., 2008, Kromhout, 2002), the 8h-TWA measurements only could give poor information on working activities involving peak exposure. For this reason, a 15min peak exposure assessment, via in-continuous, instantaneous, and direct monitoring, could help managing the risk in these scenarios.

Therefore, portable direct-reading FA monitors are of increased interest, since the analytical operations are simplified and results are obtained within a short time, with specificity, sensitivity, and consistency equal to conventional monitoring methods (Table 3). Their market is growing significantly and the global FA detector production revenue will reach 112.4 USD million by 2026, with a Compound Annual Growth Rate (CAGR) of 5.5% in 2022-2027. (Formaldehyde market - growth, trends, COVID-19 impact, and forecasts (2022-2027), News Channel Nebraska River Country, s.d.).

Table 3. In-continuous, direct reading FA monitors and their main features

<table>
<thead>
<tr>
<th>Specific</th>
<th>Device Producer</th>
<th>Price (€)</th>
<th>Dimensions (cm)</th>
<th>Weight</th>
<th>Range (ppm)</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrochemical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active filter</td>
<td>Formaldeimeter™ htv-M</td>
<td>500-1500</td>
<td>15×8×3.5</td>
<td>300g</td>
<td>0.01-10</td>
<td>2 min</td>
</tr>
<tr>
<td></td>
<td>XP-308B Formtector</td>
<td>500-1500</td>
<td>17.5×14×8.6</td>
<td>2.5kg</td>
<td>0.01–30</td>
<td>10-30 min</td>
</tr>
<tr>
<td></td>
<td>Z-300 XP</td>
<td>1500-2500</td>
<td>19×14.6×7</td>
<td>900g</td>
<td>0.01–30</td>
<td>&lt; 60 sec</td>
</tr>
<tr>
<td>Selective measurement</td>
<td>SFA30</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>&lt;0.1</td>
<td>&lt; 60 sec</td>
</tr>
<tr>
<td></td>
<td>Yes Air</td>
<td>1437-1810</td>
<td>19.7×7.8×9.8</td>
<td>600g</td>
<td>0-10</td>
<td>n.a.</td>
</tr>
<tr>
<td></td>
<td>4000 Portable Analyzer</td>
<td>5500-6500</td>
<td>17.8×10.2×25</td>
<td>2Kg</td>
<td>&lt; 0.005-2000</td>
<td>40-50 sec</td>
</tr>
<tr>
<td></td>
<td>Aeroqual Sensor</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>&lt; 0.1</td>
<td>&lt; 60 sec</td>
</tr>
<tr>
<td></td>
<td>FA Gas Sensor CB-HCHO-V4</td>
<td>500-300</td>
<td>16×19x6</td>
<td>300g</td>
<td>&lt;0.02-1</td>
<td>30 min</td>
</tr>
<tr>
<td></td>
<td>For Cubic Indoor Air Quality</td>
<td>0-1</td>
<td>&lt;60 sec</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Photometry</th>
<th></th>
<th></th>
<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>FM-801</td>
<td>GrayWolf Sensing Sol.</td>
<td>2000-3000</td>
<td>16×19×6</td>
<td>300g</td>
<td>&lt;0.02-1</td>
<td>30 min</td>
</tr>
<tr>
<td>Nemo XT</td>
<td>Ethera</td>
<td>5000-6000</td>
<td>19×13.5×7</td>
<td>520g</td>
<td>0.001-2</td>
<td>60 min</td>
</tr>
<tr>
<td>FP-31</td>
<td>RKI Instrument</td>
<td>1000-2000</td>
<td>8×15×4</td>
<td>250g</td>
<td>0.005-1</td>
<td>15-30 min</td>
</tr>
<tr>
<td>FP-330</td>
<td>RKI Instruments</td>
<td>2500-3500</td>
<td>16×19.8×26.3</td>
<td>6,5kg</td>
<td>&lt;0.02-1</td>
<td>30 min</td>
</tr>
<tr>
<td>NEMo XT</td>
<td>Ethera</td>
<td>5000-6000</td>
<td>19×13.5×7</td>
<td>520g</td>
<td>0.001-2</td>
<td>60 min</td>
</tr>
</tbody>
</table>
The electrochemical instruments are the oldest and more widespread as FA direct reading systems (Dugheri et al., 2018, 2020, Wongsa-koonkan et al., 2021, Scherer et al., 2019), due to their easy integration in occupational hygiene in the anatomical-pathology laboratories. However, they could present some issues, such as the high cross-sensitivities and related lack of specificity; to deal with it, to reduce the impact of other airborne compounds, some electrochemical instrument, such as Formaldemeter (PPM Technology, UK), XP-308B Formtector (New Cosmos Electric Co., Ltd, Japan), and Z-300 XP (Environmental Sensor Co, US) are equipped with specific filters. Other electrochemical systems use amperometric electrochemical measurement principle selective to FA with respect to other VOCs, as the SFA30 (Sensirion AG, Stäfa, Switzerland), Interscan (Interscan Corp., Italy), Aeroqual Sensor (Aeroqual, New Zeland). More recently, other technologies are used in real-time analyzers, such as infrared, photometric, differential optical absorption spectroscopy, cavity ring-down spectroscopy, fluorimetric, mass spectrometry techniques, that guarantee high performance, both in term of time response and sensitivity/specificity (Dugheri et al., 2017). These instruments can face heterogeneous exposure scenarios: thanks to their rapid response and the in continuous recording of the data (in cloud or remote storage unit), especially the newest and most expensive ones could be used to perform the long-term exposure assessment and, simultaneously, recording the data for the evaluation of the 15min short-term exposure. Moreover,
the introduction of some innovations in the occupational monitoring, such as remote control and video recording (Dugheri et al., 2021), can help pinpointing high risk tasks or worker’s dangerous behaviours. In the anatomical-pathology laboratories, where the macroscopic examination is the task at highest FA exposure (Dugheri et al., 2020) due to the posture required to obtain precision and very good visibility, the direct reading instruments could be easily integrated in the new ergonomic console. This workstations, which include ergonomic cupboard and chair, could provide at the same time a safe, and practical work area for macroscopic examination (newest ventilation systems, voice recognition technology, digital optic console, etc.) and a FA monitoring station, integrating sensors or instruments.

The levels of inhalation FA exposure in anatomical-pathology is decreasing along the years (Fustinoni et al., 2021) thanks to new safe practices, ventilation systems, the re-organization of lab spaces, improved work procedures, and awareness and training initiatives. However, due to the well-known carcinogenic and no-carcinogenic effects of FA and the related health risks, the occupational monitoring is required, allowing the assessment of long-term and short-term exposure. In sight of this and considering that the 8h-TWA is the most used metric for the occupational exposure assessment, we believe useful to set for those chemicals, with both STEL and TWA limit values, an Action Value (AV) of the 8h-TWA above which the 15min measurements are strongly recommended. For FA, using the inference equation starting from the 15min-STEL of 740 μg/m³, the AV is equal to 23.1 μg/m³.

CONCLUSION

Results obtained suggest that occupational monitoring, which comprises long-term and short term evaluation, must be recommended to obtain a complete exposure assessment, especially, for those chemicals with chronic and acute toxicity and related occupational limits. This approach, thanks to the new monitoring instruments and the possible use of the AV, can help the occupational hygienist optimizing, both in safety and economic terms, the occupational assessment and to not miss significant events.

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STRATEGIJA ZA VREDNOVANJE UTJECAJA FORMALDEHIDA NA DJELATNIKE U ANATOMSKOM PATOLOŠKOM LABORATORIJU - 2. DIO: KRATKA NASUPROT DUGE IZLOŽENOSTI

SAŽETAK: Formaldehid (FA) je štetna kemikalija koja se vrlo često koristi u anatomskim patološkim laboratorijima. Loši utjecaji FA na zdravlje zaposlenika izloženih toj tvari općenito se povezuju s dugotrajnom izloženosti, iako je i kratkotrajna izloženost vršnim koncentracijama vrlo zabrinjavajuća. Za praćenje utjecaja obično se koristi mjerenje prosjeka 8 h vrijeme-težina (TWA) kako bi se procijenila izloženost, no za kemijske tvari koje imaju akutno djelovanje izrazito se preporučuje izračun utjecaja 15-minutne kratkotrajne izloženosti. Istraživanje praćenja utjecaja FA na radnom mjestu provedeno je u jednom patološkom laboratoriju pomoću kontinuiranog, trenutnog i izravnog očitanja mjernim instrumentom u 65 radnih smjena (WS). Ni u jednoj EU granica TWA od 620 g/m³ nije bila viša. Nasuprot tome, u 40 radnih smjena prijeđena je EU granica kratkotrajne izloženosti (STEL) od 740 g/m³ i to više puta tijekom radnog vremena. Ako se ovo uzme u obzir, 8-satno TWA mjerenje daje samo šture podatke o scenariju izloženosti vršnim emisijama i o 15-minutnim procjenama najviše izloženosti, dok bi kontinuirano praćenje više pomoglo upravljanju rizikom. Uz to, preporuka za FA jest korištenje inferencijalne jednadžbe Akcijska vrijednost (AV) za 8 h-TWA iznad 23.1 g/m³.

Ključne riječi: formaldehid, praćenje na radnom mjestu, izloženost na radu

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