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THEORY, HISTORY, AND ETHICS OF CONSERVATION

Intervention vigilance in conservation: Lessons from the medical profession

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Abstract
A key responsibility of conservators is to understand the efficacy and 'safety' of the materials and methods used in conservation interventions. Material science and testing, whether in situ or on mock-ups, can support the conservator but cannot capture the remarkable diversity of real-world situations. As such, unforeseen positive and negative short- and long-term outcomes are inevitable. This paper draws upon the experience of vigilance reporting systems used in the field of medicine and proposes a system of vigilance for conservation materials and methods. Such a systematic process harnesses the observations and experiences of conservators to expand collective understanding of conservation interventions in an efficient and timely manner. Furthermore, the professional, organisational, and cultural prerequisites for successful vigilance reporting structures are discussed.

INTRODUCTION

A key responsibility of conservators, as codified by professional bodies (e.g. AIC 1994, VI), is to understand the efficacy and 'safety' of materials and methods used in conservation interventions. Safety, here, refers to the risk of negative outcomes for the objects of conservation. Material science and testing, whether in situ or on mock-ups, can support the conservator but cannot capture the diversity and heterogeneity of real-world situations. As such, unforeseen short- and long-term outcomes are inevitable. From these, new knowledge can emerge whether through reflexive analysis of individual cases or through the emergence of patterns from collective analysis.

This paper draws upon the experience of vigilance reporting systems used in the field of medicine and proposes a system of vigilance data collection and reporting for conservation materials and methods (Fornasier et al. 2018). Vigilance refers to the long-term collection of information following an intervention, but the type of information gathered will vary from case to case. Such a systematic process harnesses the observations and experiences of conservators or medical practitioners. It relies on, and promotes, a culture of openness and cooperation. The direct analogy between patients and objects is often considered problematic (Ashley-Smith 1999, 10–11). However, there are several important similarities between conservation and the practice of medicine, such as approaches to problem-solving and professional judgement in the face of overwhelmingly complex systems, competing priorities, and resource constraints, that facilitate valuable cross-disciplinary reflection (Cather 2010).[1]

This paper brings both practical suggestions and a framework through which to view practitioner-generated knowledge by drawing epistemological analogies between conservation and medicine. In particular, it takes inspiration from post-marketing drug development processes: such 'pharmacovigilance' serves the purpose of monitoring the behaviour of drugs and medical devices in real-world clinical situations once licensed for use. Here, a system of intervention vigilance is proposed and the professional, organisational, and cultural requirements for such a system to be successful are discussed along with arising ethical considerations.

THE NEED FOR MATERIAL VIGILANCE

A full assessment of any intervention methodology should consider the materials, methods, and context involved (Cather 2006). A wide range

of materials are available to conservators, with comparatively few being specially developed for use in conservation (Horie 2010, 9–10). According to their intended use, they can be divided into 'conservation materials' and 'auxiliary materials'. The former are materials which are added to the object and will remain in, or on, the object after conservation. The latter are materials used to improve the effectiveness of an intervention and are intended to be in contact with the object for a limited period of time (Redman 1999). In a collections context, this can be extended to include display and storage materials. But regardless of the conservation context, and the values driving the approach, the behaviours of materials are crucial for decision-making.

However, the understanding of the long-term behaviours of conservation materials is often poor and the understanding of these same materials in situ is invariably more limited. Part of the judgement required of conservators is whether the information available is sufficient and relevant to apply to their context (Cather 2010, 24–25). While mock-ups are valuable approximants for real objects, they cannot capture the diversity of 'real-world' situations. Deviations from expected behaviour, particularly over longer periods of time than commonly assessed, whether beneficial or harmful, are inevitable. It is exactly these observations that vigilance systems seek to capture.

The pooling of these experiences among practitioners is necessary for new collective understanding to develop. Indeed, such sharing forms a crucial element of the professional responsibility to contribute to the 'evolution and growth' of the field (AIC 1994, X).

UNFORESEEN CONSEQUENCES

The history of conservation includes many examples of interventions which have had unforeseen consequences, both positive and negative. For example, the widespread use of wax and wax-resin 'preservatives' on English medieval wall paintings in the late 19th and first half of the 20th centuries continued for decades in the face of mounting evidence of their unsuitability and devastating impact on salt-related deterioration (Cather and Howard 1986).

While each unanticipated outcome may have a different set of causes, it is important to accept these as part of practice and ensure that the whole community has the opportunity to learn from them in a timely manner – as has been discussed for the subset of such outcomes classified as errors (Marincola and Maisey 2011). There are, however, still substantial cultural barriers to the sharing of adverse outcomes in practice, despite a recognition within the profession of the values of such openness (Muñoz-Viñas 2017). The value of sharing experience lies in the steady and incremental *accumulation* of evidence, which may not appear particularly valuable in isolation. By pooling comparable evidence, accumulated over time and by different practitioners, it becomes possible to discern broader patterns. This increases the collective power of these observations and goes beyond reflexive analysis of individual cases.

CURRENT MECHANISMS FOR SHARING CONSERVATION INFORMATION

Within conservation communities there exist formal and informal systems of sharing information including the Global Conservation Forum (formerly Conservation DistList), Abstracts of International Conservation Literature (AATA Online), wikis, and traditional publishing models. Furthermore, there are substantial projects, such as Linked Conservation Data[2] aimed at making conservation documentation and data more digitally accessible (Velios 2016), which in turn depend on the ongoing development of agreed ontologies produced in the context of CIDOC, the ICOM International Committee for Documentation (Le Boeuf et al. 2018). The scale, however, of bringing such systems into use makes this a formidable task.

Calls for more extensive sharing of conservation records for the overall benefit of the profession date back at least 40 years (Organ 1980). Encouraging developments in this direction include the involvement of the British Museum, Museum of London Archaeology, National Museums Scotland, and Tate in an open access pilot repository, made possible through infrastructure built by the British Library, that may in future include all-important 'grey' literature in which so much conservation knowledge resides (Galimberti 2019). These examples demonstrate that there is a willingness within conservation communities to openly share information, but they also highlight persistent issues around copyright, professional proprietary, and liability. As noted by Kemp (2009) in reference to the British Museum (2007), there is evidence that the knowledge of possible external scrutiny positively influences the quality of conservation documentation.

INTERVENTION VIGILANCE THROUGH THE LENS OF MEDICAL PHARMACOVIGILANCE

These issues bear striking similarity to the evolution and application of knowledge in medicine, particularly in the field of drug and medical device development. This is perhaps most notable in cases of adverse events in the deployment of newly licensed drugs.

The thalidomide disaster catalysed a paradigm shift in drug regulatory processes in the mid-20th century (Vargesson 2015). Thalidomide was marketed in 46 countries between 1957 and 1961 as an effective sleeping pill and anti-sickness medication, so was taken by women early in pregnancy for morning sickness. While it performed well in this respect, reports of children born with severe limb abnormalities had accumulated by 1961. After a series of scientific investigations, it was confirmed that thalidomide was the direct cause of these severe congenital birth defects (in addition to miscarriage). Around the world, thalidomide was withdrawn from the market in most countries during 1961. By this point, more than 10,000 children had been affected.

An important consequence of this tragedy was that drug regulatory bodies began to mandate processes to proactively identify drug safety issues (collecting better quality data on drug safety throughout drug development and after regulatory approval) rather than reactively (in response to such disasters). Although requirements differ between regulatory bodies, drugs

for medical use generally pass through several well-defined stages of scientific investigation before they can be submitted for consideration of licensing (Burt et al. 2016, Medical Research Council 2020). Potential medicines must first be tested in laboratory settings (in vitro, such as cell cultures, and in vivo, using animals) to obtain preliminary information on how effective and safe the drug might be when used in humans. Following this, there are phase 0 ('micro-dosing' of the drug in healthy participants to understand drug metabolism), phase 1 (testing the clinical dose in healthy participants), and phase 2 trials (testing in patients with the relevant condition). Phase 3 trials aim to produce the best, ideally definitive, scientific evidence of the clinical effect (and safety) of the drug. They involve testing of the drug in a very large number of patients ideally from multiple areas ('multicentre trials'). As a result, they often take years to complete and are very costly.

Whilst vital for establishing the efficacy and safety of a drug, the information gained from preclinical to phase 3 trials has the significant limitation of being obtained from use in a very narrow group of participants – most commonly, otherwise healthy young men. Once a drug has been licensed, the population of so-called 'real-world' patients who will use a drug is far more diverse and, until this point, relatively untested. The incidence of long-term risks and benefits, rare side-effects, properties in underrepresented groups (women, pregnant women, children, those with other medical conditions, ethnic groups underrepresented in trials), and the effects of simultaneous use with other drugs (co-medication) are typically only revealed once drugs are in use in a post-licensing setting. For these reasons, phase 4 trials (also referred to as post-marketing surveillance or pharmacovigilance) are now an integral element of continuous collection of data about a drug or medical device in real-world settings. At its core is an acceptance of the central role of timely information sharing to minimise harm.

Another, less well-known example demonstrates the importance of this process. Halofantrine is an antimalarial drug which was approved for use by the Food and Drug Administration (FDA, USA) in 1988 (Croft 2007). Following this, case reports accumulated associating halofantrine with the sudden death of patients being treated for malaria. It emerged that halofantrine can, very rarely, provoke a potentially fatal disturbance in the heart's rhythm, particularly in those who have recently been treated with a specific antimalarial which, in combination, propagates this adverse effect. These 'safety signals' were identified and, as a result, regulatory authorities changed the recommendations for use. This example highlights the limitation of clinical trial data for identifying very rare events arising from heterogeneity in human populations.

MECHANISMS OF PHARMACOVIGILANCE REPORTING IN MEDICINE

A variety of reporting systems have been developed around the world. In the United Kingdom (UK), the Yellow Card Scheme was established in 1964, again in response to the thalidomide disaster (Medicines and Healthcare products Regulatory Agency 2020). Principally, it involves

the reporting of suspected or confirmed adverse events by healthcare professions and patients from medicines and medical devices. Reports can be submitted on paper, online, or via an app. The frequency of reporting events is analysed automatically, and safety 'signals' are highlighted when a particular threshold for concern is reached. These events are then investigated by a specialist team, and, if required, the resulting action is communicated to appropriate professional bodies and to the public. A similar system called MedWatch has been established by the FDA (FDA 2020).

THE LIMITS OF TRIALS: COMORBIDITIES AND CONCURRENT CONDITION PHENOMENA

The limitations of phase 3 trials are familiar to conservators and conservation scientists in the use of treatment tests on mock-ups. Attempts to gather data which produce statistically valid conclusions often reduce diversity in the test population. In the same way that certain comorbidities might not be represented in clinical trials, some concurrent condition phenomena will not be considered or accounted for in material testing. For example, in testing the efficacy of a consolidant for lime plaster, the presence of soluble salts may impact the performance of the consolidant through unanticipated reactions or the consolidant vehicle might mobilise and redistribute the salts.

As an example, one methodology for consolidation is the application of barium hydroxide/ammonium sulfate to address 'sulfation' and improve cohesion, sometimes known as the 'Florentine method' (Matteini 1991). This requires transport of highly alkaline solutions *through* the paint layer. Intended to convert gypsum (considered to be an alteration product of lime plaster) to effectively insoluble calcium and barium compounds, the basic conditions can, however, be incompatible with (non-)original materials like nitrate salts due to resultant formation of barium nitrate. Application to a painting of San Antonio Abate in the church of San Pietro, Quaracchi (Italy), resulted in the change of a green pigment to blue and, over two years, back to green (Dei et al. 1998). The green pigment was later identified as paratacamite, $Cu_2(OH)_3Cl$ (present as alteration from azurite), which was transformed to blue $Cu(OH)_2$ and then apparently reverted back to paratacamite.

The case study was reported in 1987 but took over a decade for the unintended consequences to be understood and shared. Interestingly, personal communications cited in Dei et al. (1998) attest to this phenomenon having been observed in 'many other wall painting conservation projects', of which only one was reported in the literature, and furthermore only in a limited manner (Rosi 1987). More timely sharing of this phenomenon may have led to faster identification of this contraindication for the intervention and the prevention of further cases.

PROFESSIONAL, ORGANISATIONAL, AND CULTURAL ASPECTS

To enable a system of material vigilance to have a timely impact on practice, aspects of contribution, access, and governance/maintenance need to be

addressed. We identify the following considerations, the realisation of which could take a variety of forms for conservation:

- **Contribution** is a professional responsibility and ethical imperative. Failure to contribute leads to duplication of work, wasted resources, and loss of impact of knowledge.
- **Contributors** require appropriate training to be active members of the community. Conservators, like clinicians, do not need to be scientists but do need to contribute appropriately with observations clearly separated from interpretation.
- **Platforms** must support efficient contribution and access. These require funding and oversight.
- **Data curation** is necessary to maintain trust and standards.
- **Education** should ensure that practitioners can understand, apply, and access information.
- **Access** should be global and free at the point of use.

Delving deeper into the issue of contribution, experience can again be drawn from the medical profession. During the infancy of evidence-based medicine, it was argued that failure to report evidence that had been obtained or generated (in particular in the context of clinical trials) should be considered 'scientific misconduct' (Chalmers 1990). This is because selective failure to report data distorts, or biases, the body of data and the resulting analyses and conclusions. For example, a tendency to report results which show an intervention is effective, rather than ineffective or inconclusive, means that the overall picture of the evidence is one of falsely high efficacy. This, in turn, can lead to avoidable, potentially harmful treatment decisions, whether in relation to a patient or a cultural heritage object. It results in wasted resources and limits the timely development of our collective knowledge. This principle extends to vigilance reporting, the importance of which is evidenced by the mandatory requirement of doctors in the UK to report drug and device safety events (General Medical Council 2020). Implicit in this is the ethical obligation to make data or information available for others to benefit from.

In phase 1–3 clinical trials, there are clear, predefined outcomes for which data will be collected and should be reported. However, in phase 4 this is not the case, and it can be difficult for the individual practitioner to know what they have a responsibility to report. Phase 4, pharmacovigilance, is more akin to conservation activities where the threshold for reporting may be unclear. Given that the value of reporting may not become clear until years later, there is a strong case for erring on the side of reporting when in doubt. While some cases, such as the unexpected outcomes of consolidation detailed in Dei et al. (1998) as discussed above, appear to have clear reporting value, many cases will rely upon the judgement of individual practitioners. Countervailing forces for non-reporting include intentional concealment, e.g. to retain competitive advantage or conceal a 'mistake', and neglect, which might arise from an unwillingness to allocate resources to reporting. There is a clear role for conservation communities in actively directing reporting priorities, which will change in response to prevailing concerns and practices.

IMPLICATIONS FOR CONSERVATION

What might a conservation equivalent of pharmacovigilance look like? Many different models of contribution, access, maintenance, and funding could be successful. For example, Kemp's (2009) advocacy for wiki-based open conservation records which document decision-making processes would provide a natural foundation for the recording of vigilance data. A further advantage of platforms that are globally, freely accessible is the potential to engage with practitioners around the world as both users and contributors. By avoiding barriers associated with traditional publishing models, the information collected would be more diverse and more representative of global practice. Of central importance is prioritising information that helps the profession to assess intervention materials and methods in the long-term and in an open, inclusive, and timely manner.

Contribution should maximise the value of information and minimise the burden on contributors. As a field, conservation practitioners should recognise that some interventions will result in unexpected outcomes and, furthermore, must have the confidence and honesty to allow our colleagues to learn from these events (Marincola and Maisey 2011). Engagement with such systems would require some space in already overstretched conservation curricula (Cather 2000).

The discussion here has focussed on conservation and auxiliary materials for remedial interventions, but this framing of information may be extended to display and storage materials in a collections context. The community resource database of Oddy tests hosted by the American Institute for Conservation embodies the organisational and cultural aspects discussed above (AIC 2018). This database, which provides information on the safety of materials used in or around objects, might be extended to capture vigilance data – i.e. how these materials perform in the real world.

THE ROLE OF PROFESSIONAL BODIES

Professional bodies such as the AIC already support collaborative knowledge sharing and generation, such as through the Oddy test database discussed above. However, there remains a significant challenge in securing funding for long-term understanding and monitoring (Cather 2010, 23). At present, the long-term assessment of conservation interventions, whether preventive, passive, or remedial (Arnold 1996), remains the preserve of only the most well-resourced organisations and fastidious practitioners. Professional bodies must play a role in a cultural shift and, where necessary, apply regulatory pressure towards assessment of interventions in the long term. The materials vigilance approach is one aspect of this much more substantial issue.

This paper makes appeals to standards of professional responsibility so cannot avoid considering the ever-present issues of professional definition and protection, both of which are much less well established in conservation than in medicine. In this context it may be difficult for conservators, especially those in private practice, to justify the resources they need to contribute to the development of the profession. This represents a clear need for professional bodies to support the involvement of a diverse pool of conservators from across our profession.

CONCLUSION

This paper has made a case for the use of long-term vigilance structures in conservation. These rely on the contribution of conservators to better understand the behaviours of materials in a variety of real-world contexts. In examining historic conservation decision-making through the lens of regulation of medicines, it has been shown that there are similar limitations to safety and efficacy testing in conservation and medicine. Perhaps the most important of these is the inevitable failure to capture the full diversity of circumstances for which the materials, or drugs, are eventually utilised. The intellectual and professional framework of drug trials could be of value in the development and effective and safe use of conservation interventions and materials. Collection of this information requires funding to facilitate reporting, dissemination, and updated guidance based upon real-world experience.

NOTES

[1] Ilsa L. Haeusler and Joshua A. Hill contributed equally to the conception, development, and production of this manuscript.

[2] See https://www.ligatus.org.uk/lcd/

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