

MOVING FROM EFFICACY TO SAFETY:

A CHANGING FOCUS IN THE STUDY OF ASIAN MEDICAL SYSTEMS

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After living and studying in India for a decade, I enrolled in the Master's course in Medical Anthropology at Oxford in 2002 as one of twelve students from five countries. Studying at Oxford was such an inspiring experience that I continued with a D.Phil. in Social Anthropology, researching longevity practices and concepts of the life-span in Tibetan societies in India (Gerke 2012a). I then taught at three universities in the USA and Germany, and pursued a post-doc at the Humboldt University, Berlin, on detoxification methods in Tibetan pharmacology and on how ideas of toxicity are translated cross-culturally (2011-2015). Critical course discussions that we had at Oxford on efficacy made me look at issues of safety and helped me think anthropologically about toxicity. How can we study toxic ingredients of medicines with research methods specific to anthropology in the absence of laboratories and biomedical testing tools? Looking at changing anthropological approaches to efficacy and safety are my entry points for this article, which provides some of the groundwork necessary to address questions of how Tibetan doctors translate their ideas of toxicity and detoxification to a Western audience.

Introduction

In relation to my postdoctoral project on concepts of toxicity and purification in Tibetan medicine, I have come to re-think issues of 'efficacy' and 'safety' that we discussed during the medical anthropology course at Oxford in 2002/03. I asked myself how these issues have been dealt with in the discipline since then and how they have affected Asian medical traditions.¹ While reading through the literature, I noticed a certain shift of focus from 'efficacy' towards 'safety,' which I will discuss in this paper, specifically in relation to toxicity in Tibetan medicine.

¹ The German Research Foundation (DFG Project No. 53307213) kindly funded this research.

Efficacy was not of primary interest in early medical anthropology, but it has become so more recently, as was evident in the syllabus of the Master's course in Medical Anthropology at Oxford in 2002. In the late 1980s, efficacy was listed as the fifth main theme in pharmaceutical anthropology (van der Geest 1988: 331). At that time, efficacy studies mainly focused on double-blind randomized control trials (RCTs) and placebo studies (ibid.: 343-6). In the Master's course, we analysed RCTs in order to understand how they culturally determine efficacy. RCTs also highlight how profession-specific understandings of efficacy are. In ethnopharmacology, efficacy was considered 'the organizing paradigm perhaps most central to ethnopharmacology' (Etkin 1993: 99). During the Master's course, we learnt that 'therapeutic intentions are culturally constructed, even such seemingly objective aspects as "efficacy"' (ibid.: 100). We were trained to be aware of the complexities surrounding efficacy, knowing that—to take one of Etkin's examples—'one cannot evaluate in the laboratory the efficacy of a plant used against swelling due to infection in the same way that one evaluates a plant used to treat swelling caused by witchcraft' (ibid.). As anthropologists, we were also made aware that pointing out efficacy as a 'cultural artefact' to health planners has often been the 'thankless task of the anthropologist' (van der Geest 1988: 346).

My thought process was partly inspired by the new interdisciplinary collaboration between ethnobotanists and medical anthropologists, visible in recent publications such as *Plants, Health and Healing* (Hsu and Harris 2010). In her introduction to this book, Hsu observes that so far the anthropology of pharmaceuticals has not focused on the 'materiality of drugs,' but rather on meaning, socio-economic and cultural interpretation, symbolic efficacy and social efficacy (Hsu 2010: 23). I agree with her critique that 'the pharmaceutical anthropologists have left the study of physiological efficacy to biomedicine' and have instead

‘accounted for socio-cultural aspects’ (ibid.). In the following, I will look at the importance of physiological efficacy for anthropological studies on pharmacology in more detail.

My current research project investigates Tibetan medical ideas of toxins/poisons (Tib. *dug*) and how Tibetan pharmacologists explain the detoxification (Tib. *dug 'don*)² of substances. These ideas are often expressed in terms of whether their detoxified medicines are ‘safe,’ especially when ingredients involve poisonous plants, mercurial compounds, or other metals. The safety concern is not so much an issue within Tibetan medical communities themselves, where through experience these medicines are thought to be ‘safe,’ but is framed as part of their interactions with biomedical standards and demands, as well as Tibetan interests in exporting their medicines to countries where their ‘detoxified’ ingredients might be considered ‘unsafe.’

How can anthropologists study the physiological efficacy and safety of such detoxified Tibetan medicines? So far, they have studied the political efficacy of detoxified Tibetan pills and how these medicines are employed to strengthen Tibetan identity in exile (Kloos 2012). Widespread Tibetan practices of poisoning, which involve ideas of stealing the life-force and fortune of the person who is being poisoned, have been ethnographically researched (da Col 2012). However, we know little of what is considered a *dug* in Tibetan pharmacology and how it affects the physiology of the body, especially from a Tibetan medical perspective, which does not strictly follow organ-related ideas of efficacy, but views the body in terms of balancing elements and ‘humours.’ When it comes to *dug*, physiological efficacy seems to be inevitably linked to issues of toxicity and safety, which were not emphasised in pharmaceutical anthropology until recently.

² Processes of *dug 'don* largely involve the cleaning of raw materials by removing those parts that are either considered harmful or even poisonous, and those parts that would interfere with or reduce the efficacy of the beneficial parts.

The move towards 'safety' and what it implies

Over the past decade, it seems that safety has been given a stronger emphasis than efficacy by the WHO and in literature on 'traditional' medicine. To understand this shift, first we need to analyse what 'safety' entails in so-called 'traditional medical systems,' which in most cases—taking into account today's globalized world and heterogeneous clinical modes—can hardly be called 'traditional' anymore. The complex of 'Tibetan medicine' serves as one example here for the development of a medical system in which the borders between 'traditional' and 'modern' have become very fluid, also influencing the ways in which contemporary Tibetan doctors translate and negotiate biomedical concepts within their 'traditional' epistemologies and vice versa. Such increasing heterogeneity also affects practitioners' perceptions of safety.

There is a widespread perception, if not misconception, that 'traditional' remedies are 'safer' because they are 'natural' (Elvin-Lewis 2001: 141), assuming an almost essentialist version of 'safety' directly linked to the highly constructed notion of 'nature'. However, this presumption is being increasingly scrutinized. I have seen Tibetan doctors warning patients that their 'natural' remedies can be 'unsafe' and cause adverse effects if wrongly administered.

There are a variety of conditions that influence what makes a substance 'toxic' and 'unsafe' in a certain context. Safety is not only a matter of efficacious ingredients or toxicity. The Master's programme at Oxford discussed safety in the context of the biological and social aspects of drug-taking, showing how this inevitably leads to varying perceptions of safety. We were made aware of the situatedness and the reasons why, for example, pharmaceuticals are perceived as more risky than traditional medicines. One reason that

traditional Asian medicine is considered safer is that it matches an individual's prescription with his/her constitution. It is thus a 'personalized medicine,' as is characteristic of Ayurveda, Tibetan and Chinese medicine, and which is becoming increasingly popular.³

This kind of 'situatedness of safety' does not necessarily feature in the list of herbal medicine safety issues identified by the WHO, namely contamination with heavy metals and other hazardous substances, adulteration, wrong substitution, incorrect dosing and interaction with other medicines (WHO 2004: 2). Below are a few examples of each of these points, and to this list I would add two more: i) 'traditional processing methods,' of which we know little and which are essential to understand emic explanations of safety; and ii) issues of commodification and economic expansion. Moreover, safety is also defined by political circumstances that influence these WHO safety guidelines (and why certain topics are included and others are left out), which might neglect or even contradict localized perceptions of safety.

Contamination is one of the safety issues linked to Good Manufacturing Practices (GMP). GMP practices are indirectly concerned with toxicity because they aim at clean manufacturing, the main aim being the avoidance of contamination, e.g. with heavy metals. For example, a long-term intake of herbs contaminated with heavy metals can have toxic effects.

Substitution. Misidentification of plants can lead to toxicity. The fact that the erroneous substitution of one plant for another can cause toxic effects was shown in the case of Chinese Herb Nephropathy (CHN) caused by a Chinese weight-reducing pill made with the wrong substitutes (Hsu and Barrett 2008: 354).

³ This is evident, for example, from conferences, such as that on 'The quest for personalised health: exploring the emergent interface of East Asian medicines and modern system sciences' organized by the EASTmedicine Research Centre at the University of Westminster and the School of Life Sciences, June 2011.

Dosage. Safety is situational: a substance can be efficacious at a certain dosage and toxic at another. Long-term intake or over-dosage of herbal medicines can make them toxic. Some Tibetan doctors resist the commercialization of Tibetan medicine as over-the-counter products precisely because, through self-medication, the dosage might not correspond to the individual constitution of the patient and could cause adverse effects.

Interaction with other medicines. Relationships between ingredients can influence the overall toxicity and efficacy of a drug. For example, Tibetan medicinal plants tend to be given in combination with other substances, not in isolation. Tibetan doctors I interviewed consider single ingredients ‘toxic’ and unsafe, while in combination they are considered more ‘efficacious,’ since one substance can disarm the potential toxic effect of another. When herbal preparations are combined with biomedical drugs—something patients tend to do frequently in pluralistic medical settings—their physiological interactions can cause toxicity (e.g. Elvin-Lewis 2001: 156).

‘Traditional’ processing methods. In Tibetan pharmacology, cleaning raw medicinal materials, such as removing the bark or a kernel, is considered a part of ‘detoxification,’ since these materials—also called *dug*, although they are not considered poisonous—are more difficult to digest and would reduce the efficacy of the potent part of the plant. Mercury (Tib. *dngul chu*), which is known to have three types of *dug* and is considered highly poisonous, has to be transformed into a mercury sulphide ash through elaborate processes in order to be considered ‘safe.’ This is similar to Ayurvedic and Chinese practices of using mercury almost exclusively in the much less toxic, largely insoluble forms of mercury sulphide. In Tibetan medicine, toxicity is also explained in terms of digestion. Tibetan doctors diagnose and treat the digestive strength of a patient who has been affected by a *dug*, since they think that the

ability to handle *dug* depends on the power of one's digestion. The stronger one's digestive power, the better one's ability to handle a *dug*.

Commodification and economic expansion. For countries where 'traditional medicine' is a national asset, such as China, safety is also an issue of economic expansion; China wants to play a significant role in the commodification and globalization of traditional Chinese medicine (TCM) and is therefore pushing for the regulation of Chinese medicinal substances. This economic expansion is also evident in the ways in which hospital pharmacies throughout Tibet have been converted into pharmaceutical companies, producing commodities for a nationwide market (Saxer 2013). In support of such expansions, the Chinese Pharmacopoeia Committee has reduced the permissible amount of mercury and arsenic used in Chinese medicine recipes twice in recent years (Wu et al. 2008: 839). However, Chinese manufacturers do not necessarily follow GMP guidelines when it comes to profitable medicines, such as Tibetan 'precious pills' (Tib. *rin chen ril bu*), which contain mercury sulphide. Some of the mercury sulphide-containing compounds are considered 'national heritage drugs' and have so far remained outside GMP regulations (Saxer 2013: 74).

These examples show that safety is situational as well as multi-dimensional and that it is increasingly becoming a major concern. Anthropological studies of safety, while they cannot be seen in isolation from ideas of efficacy, should address such issues by unravelling their linkages to local and global settings.

Links between safety, toxicity and 'rejuvenating' tonics

Why is it that across Asia toxic substances are often considered vitalizing? In Indian alchemical and Ayurvedic contexts, mercury is attributed with rejuvenating properties as reflected in its mythological and tantric correspondence to Shiva's semen, though it is only

potent in combination with sulphur, which symbolizes his consort's blood. One of my research aims has been to uncover the rationale behind Tibetan practices with mercury and their inherent assumption that mercury is especially vitalizing when it is 'tamed' and transformed into the most potent rejuvenating elixir (Gerke, in press)

While it could be argued that use of the term 'rejuvenation' is a modern esoteric concept—often used for commercial purposes—it is important to know that rejuvenation is also an articulated aim in some Asian medical practices. That does not mean that taking 'longevity pills' necessarily leads to a long life. For example, in medieval China, Tang ascetic intake of 'longevity pills' was thought to lead to immortality through self-poisoning (Hsu and Barrett 2008: 355). However, Tibetan medical texts on 'treating the aged' (*rgas pa gso ba*) list vitalizing drugs and clearly articulate their rejuvenating effects. Tibetan technical terms that are employed in such longevity contexts usually have a variety of other meanings as well, but tend to be translated in terms of 'rejuvenation.' For example, the term *chulen* (*bcud len*), which literally means 'essence extraction,' refers to pills made from extracts of stones, flowers, minerals, etc. While such extractions have been used to prevent ageing and revitalize the body, they also have significant religious, pharmacological and nutritional meanings and purposes. Nevertheless, the term *chulen* and concepts surrounding it have recently been re-invented in a process to market over-the-counter 'rejuvenating tonics' (Gerke 2012b).

'Rejuvenating' products touch on issues of safety precisely because they often contain what we relegate to the realms of toxicity. In Asia, they usually contain higher levels of heavy metals than other supplements. One study of Ayurvedic *rasaśāstra* 'rejuvenating' supplements sold online in the US showed that they contained the largest amount of metals among the surveyed supplements, i.e. 40 percent; 20.7 percent of the samples were found to

have potentially toxic levels of lead, arsenic or mercury (Saper et al. 2008: 918). However, one major shortcoming of Saper's study is that the investigators do not differentiate between the types and 'chemical species' of heavy metals used. Talking simply about 'mercury' sounds alarming and glosses over the fact that it is mostly used in the form of mercury sulphide, of which, once ingested, less than 0.2 percent is absorbed by the body (Liu et al. 2008: 813). The problem is that there are hardly any studies on the different 'chemical species' of metals used in *rasaśāstra*, something the authors themselves acknowledge (Saper et al. 2008: 922) but fail to include in their methodology. When it comes to mercury, this is a significant lapse, since the absorption of mercurials by the body—and thus their 'physiological efficacy'—varies from 0.2 to 95 percent, depending on their chemical form (Liu et al. 2008: 813). Recently, some scientists have moved towards analysing the 'chemical species' of metal ingredients in traditional medicines. One Chinese study, which uses cell cultures to determine levels of toxicity, argues that the 'chemical forms of metals are an important factor in determining their toxicity in traditional medicines' and that, for example, both cinnabar (red mercury sulphide, HgS) and realgar (red arsenic, As₄S₄) 'are much less toxic than well-known mercurial and arsenicals' (Wu et al. 2011: 839). While such studies give a more nuanced perspective on the physiological efficacy of mercurial medicines, they do not satisfy hard-core science toxicity regulations.

Tibetan pharmacologists have told me that the medicinal 'power' (*nus pa*) of mercury is enhanced when properly 'purified' (*dug 'don*) and 'tamed' (*'dul*) through elaborate pharmacological processing methods. Its ash mixture is then added as a base material to other medicines, such as some 'precious pills.' These 'precious pills' are not only considered necessary to treat severe, especially 'modern' diseases, but are equally popular as 'rejuvenating' tonics or talismans among Tibetans and more recently also Chinese, due to the

additional blessed substances they contain. Moreover, because of their ‘precious’ ingredients, they are more costly and time-consuming to produce, require specialized pharmacological knowledge that few possess, and are therefore sold at higher prices than basic herbal remedies. Thus, ‘precious pills’ form the pinnacle of Tibetan pharmacological knowledge and increase the prestige of the institution and doctors who are able to manufacture them (Kloos 2012). While medical practitioners consider these pills their strongest therapeutic tools, patients perceive them as an embodiment of vitality, health and ritual blessings.

These examples from my research highlight the interrelationships between toxic ingredients and profitable manufacturing practices of contemporary ‘rejuvenating tonics’.

The politics of toxicity and safety

Kadetz concluded from his research on traditional medicines in the Philippines that safety is not a universal concept, but perceived variously within local practices. ‘The predominant sentiment was that unless a local practitioner gives one reason for concern, there is no conception of risk with local practices’ (Kadetz 2014: 87). While the concept of risk is often framed differently locally – for example, in terms of ‘fortune’, ‘luck,’ or ‘fate’ – it becomes a global issue when pharmaceuticals are sold abroad and are found not to meet the required safety standard, often because of toxicity concerns. Therefore, Tibetan doctors in India have invited foreign scientists to analyse the safety of their mercury sulphide-containing ‘precious pills’ (e.g. Sallon et al. 2006); they have confidence in their processing methods and consider them safe, but they need ‘scientific evidence’ for trading with the outside world (Gerke 2013).

The WHO has mentioned the term ‘safety’ with great frequency in its publications since the Traditional Medicine Unit came under the Department of Essential Medicines of the

WHO, which attests to an increasing effort to control and define what is safe in non-biomedical practices, also paralleling the growing commodification of the herbal industry in Asia (Kadetz 2014: 85). When it comes to toxicity, to date WHO guidelines mention toxic metals only in the context of contamination; as far as I know their widespread use as medicinal ingredients, especially in Asian medicines, has yet to be addressed. This shows that, on the one hand, the WHO is keen to define and control what is considered ‘safe,’ while on the other it reduces the use of some ‘detoxified’ substances in non-biomedical practices to issues of contamination without inquiring into their potential efficaciousness. Similarly, in the UN’s legally binding treaty to ban mercury, passed in 2013—in itself meaningful—the medicinal use of much less toxic mercury sulphide (cinnabar) in Asian medicines does not feature (United Nations 2013). However, the treaty has exempted the use of mercury in ‘products used in traditional or religious practices’ (ibid. 2013: 22), which could arguably include the cinnabar-containing drugs of Asian medical traditions.

Toxicology studies situated around chemical industry-funded ‘special interest science’ (SIS) show that enormous political and economic interests are at play in the struggle to define toxicity. In studying these, we should remember that our concepts of risk and safety are not universally shared.

Conclusion

The demand for Asian medicines and health tonics is enormous, and the markets for them are profitable. The consumer wants to be ‘safe’ taking these drugs, especially after the increase in published reports on toxicity. Pre-clinical safety evaluations are generally performed for new medicinal herbal products following the standards set by respective governments. Such safety standards have been extensively outlined by the WHO for *herbal* medicines, but not for the

use of *metals* in ‘traditional medicine.’ How can medical anthropologists study these issues with research methods specific to anthropology in the absence of laboratories and biomedical testing tools? I can see several avenues.

Medical anthropologists could look more directly at the material substances of pharmacology, write ethnographies of the use of such substances, and analyse their links to issues of safety and toxicity. Ethnographic studies offer more nuanced approaches to better embrace the interplay between the biomedical-pharmacological-material worlds of the substances themselves and their socio-cultural, economic and political aspects. They thus elucidate how substance classifications are as culturally specific as are their manufacturing techniques, and they highlight the perceptions of the substances’ potential toxicity and the assessments of their physiological efficacy.⁴ Risk studies have already made some use of ethnographic methods to assess the cultural and religious meanings behind heavy metal use (Riley et al. 2006).

Ethnographic research questions on potentially toxic pharmacological substances could include, for example: How do Asian pharmacologists reason about the safety of substances that from a biomedical perspective are considered toxic? When is a substance considered ‘toxic,’ and when is it ‘safe’? On what pharmacological and physiological principles are their processing methods based? I have tried to show that the understanding of what makes a substance ‘toxic’ depends on many things, including issues of contamination, substitution and dosage, interaction with other medicines, ‘traditional’ processing methods, commodification and economic expansion, and also the political issues involved in WHO and UN safety efforts.

⁴ With regard to herbal drugs, such culture-specific changes in preparation and therapeutic outcomes across history have been described, for example, for the herb *Artemisiae annuae* in Chinese materia medica (Hsu 2014).

To document and analyse how pharmacologists of Asian medicines define and explain toxicity, the physiological efficacy of potentially toxic ingredients, and how governments and the pharmaceutical industry direct and fund toxicology studies will be an important contribution to the debate on safety studies relating to Asian medicines. In my current research project, I show that what is considered a *dug* in Tibetan medicine is by definition not simply ‘toxic.’ In this way, anthropological studies of both ‘toxicity’ and ‘toxic’ substances as such can contribute considerably to a more nuanced understanding of Asian pharmacological practices and to safety debates on Asian medicines.

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