



# Unregulated herbal products and food supplements: Assessment of safety

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## ABSTRACT

There is extensive and rapidly growing use of a wide range of T and CM therapies worldwide. Objective: assessment of safety issues of traditional and complementary medicine (T and CM) practices and products and its related factors.

Methods: The current literature was searched for evidence of and factors associated with the safety of T and CM practices and products.

Results: Aspects of safety could be explained by multifactorial elements that grouped as:

- 1) Factors related to unregulated herbal products and food supplements.
- 2) Factors related to conventional providers of healthcare.
- 3) Factors related to unregulated providers of T and CM.
- 4) Factors related to users of T and CM.

Conclusion: Assessment of safety and risk of T and CM practices and products depend on combinations of many factors. Governmental authorities need to work on all of these factors collectively to ensure safety of T and CM use.

**Keywords:** Safety, Traditional medicine, Complementary medicine

## INTRODUCTION

Recently, the use of T and CM therapies in Saudi Arabia was increasing (Al-Faris E et al., 2008). T and CM practitioners and conventional health care professionals had little knowledge of T and CM modalities and less understanding of safety considerations related to their use (AlBedah AM et al., 2012). Surveys done locally in Saudi Arabia revealed extensive and rapidly growing use of a wide range of T and CM therapies by 75% of Saudis. In fact, more than half of patients receiving conventional medical care now also use T and CM care (Al-Bedah AM et al., 2013).

Aspects of safety issues related to T and CM have been somewhat neglected. Safety of T and CM practices and therapies is not regulated worldwide. In many instances, there is a lack of information on a particular product or practice until adverse events against are brought to governmental authorities.

Healthcare providers should familiarize themselves with T and

CM practices and products their benefits and risks to best care for their patients (Alrowais and Alyousefi NA, 2017).

It would be helpful in day-to-day clinical practice if it were possible to define a standard level of safety or acceptable risk for all practices, herbal and nutritional products, and procedures (Mohamed Khalil et al., 2014). This is an unrealistic goal, because an assessment of safety and risk depends on combinations of many factors hence this review.

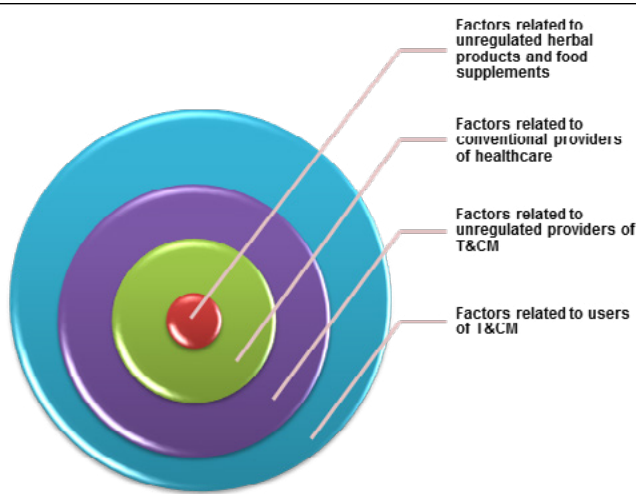
## METHODS

The current literature was reviewed for evidence of and factors associated with the safety of T and CM practices and products. Literature search included PubMed, Research gait, Google Scholar, OVID and Cochrane library databases for systematic reviews and meta-analyses, randomized controlled trials, case series, case studies, and case reports published in English from inception through September 2020. Search was conducted to obtain data on the safety of T and CM products and practices

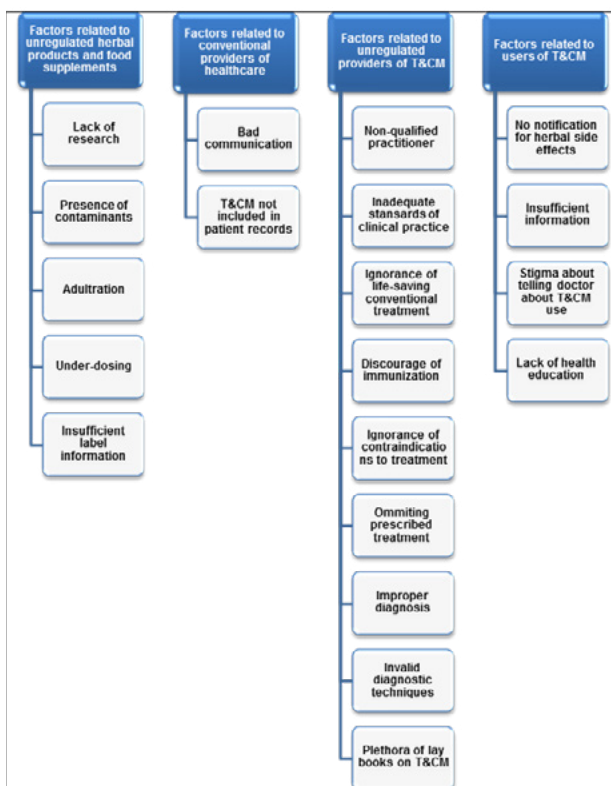
and any reported toxic effects, side effects, adverse events and presence of contaminants and their related associated factors.

**RESULTS**

Aspects of safety and associated factors can be grouped as follow (Figures 1 and 2)



**Figure 1:** Different aspects of safety for T and CM practices and products.



**Figure 2:** Factors associated with safety for T and CM practices and products.

**Factors Related to Unregulated Herbal Products and Food Supplements**

1. Herbal medicinal products (HMPs) are marketed in most countries as food supplements which lack rigorous regulation required for conventional medicinal products especially for safety and quality of the product (Khlood M. Aldossary, 2019).
2. Some contaminants have been found in HMPs such as microorganisms, microbial toxins, pesticides and herbicides, fumigation agents, radioactivity and heavy metals which are more prevalent in Asian countries (Alghamdi MA, 2018).
3. Adulteration of HMPs with non-declared herbs or conventional drugs e.g. acetaminophen, hydrochlorothiazide, indomethacin, phenobarbital, sildenafil and corticosteroids (Mainardi T et al., 2009).
4. Under-dosing of HMPs where the active ingredient content differs marginally from label claims (Driver S and Williamson E, 2013).
5. The label information is insufficient or inconsistent (Al-Dossari DS et al., 2016).

**Factors Related to Conventional Providers of Healthcare**

1. Patients fail to inform their physician of their T and CM use (Abdullah Al-Rowais et al., 2012). Either physician does not ask or the patient lacks the motive to tell his physician. From previous literature, 37% of patients start discussion with their physicians about T and CM use (AlBedah AM and El-Olemy AT, 2012).
2. Doctors tend to omit asking about T and CM use or documenting T and CM use in patients' records (Qureshi NA et al., 2015).

**Factors Related to Unregulated Providers of T and CM**

1. T and CM providers are predominantly non-medically qualified practitioners (Paul Posadzki et al., 2014).
2. Some T and CM providers do not adhere to adequate standards of clinical practice (Al-Bedah AM et al., 2016).
3. T and CM providers may delay or hinder access to potentially life-saving conventional treatment (Al Mansour MA et al., 2015).
4. Some T and CM providers' advice against any type of immunization (Al-Bedah AM et al., 2015).
5. Some T and CM providers not screening for contraindications for treatment (Sohaibani et al., 2015).
6. Changing or omitting prescribed treatment (Al-Rukban MO et al., 2012).

7. Some T and CM providers could be unable to adequately diagnose medical problems (Al-Ghamdi et al., 2016).
8. Use of not risk free or invalid diagnostic techniques (Al-Bedah AM et al., 2015).
9. Plethora of lay books on T and CM now available in every high street book-store (Eliedi A et al., 2016).

#### Factors Related to Users of T and CM

1. Majority of T and CM users do not consult for herbal serious adverse effects (Khlood M. Aldossary, 2019).
2. Majority of T and CM users employ T and CM with insufficient information (Yahya OA et al., 2017).
3. Most T and CM users fail to tell their doctor to use folk and complementary medicine practices for fear of being reprimanded (Al-Bedah AM et al., 2015).
4. Most T and CM users didn't ask about certificate, qualification of T and CM practitioners and their license (Al-Bedah, A M, 2010).

#### CONCLUSION

Assessment of safety and risk of T and CM practices and products depend on combinations of many factors. Governmental authorities need to work on all of these factors collectively to insure safety of T and CM use.

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