

- c. 包含および除外のチェック（中風前兆[Prodrome of wind stroke disorder]など）
- d. グループ分けのチェック（原理に基づく混合パターン[Mixed Principle-based patterns]など）
- e. 海岸線（**shoreline**）のチェック（陰虚[Body Yin deficiency]など）

## PAG 協議に向けた疑問および問題点

1. 原理に基づく混合パターン (**Mixed Principle-based patterns**) : グループの説明およびカテゴリーの配置を明確化する。現在、原理に基づく混合パターン (mixed principle-based patterns) には 2 種類ある。すなわち、原理に基づくパターン (Principle-based patterns) と「中間的な」原理に基づくパターン (“in between” Principle-based patterns) の組み合わせである。編集責任者との協議の結果、2 種類とも事後結合 (post-coordinated) の概念として表せることが明らかになった。
2. 環境要因のパターン : 見出しの基本語および同義語を明確化する。環境要因パターンの定義案を検討する。
3. 伝統医学 (TM) と西洋医学 (WM) のカテゴリーの明確化 : 伝統医学 (TM) および西洋医学 (WM) のカテゴリー間の同一性のレベル (すなわち同等性に基づく) を明らかにする。ある特定の定義が、どのような場合に伝統医学および/または西洋医学の概念や用語を指しているかを明確にする。次いで、見出しおよび定義において西洋医学の疾患、伝統医学の疾患およびパターンに言及し、それらを区別するための命名規則を考案し、実施する。
4. どこで、また、どのような形式で、セクションの説明や、クラスの定義および重要な用語 (陽の性質 [Yang nature] の意味など) に関する追加的な詳細情報や解説を示すべきか (伝統医学の章の用語集、リファレンス・ガイドなど)。

## 構成原則および分類構造の全般的概要および伝統医学の章に固有の概要

### 序文

1. ICD-11 第 1 巻には、死亡率報告と罹患率報告のいずれにおいても用いられる、ICD-10 の 3 文字および 4 文字レベルと同等の疾患単位 (entities) の共通線状化 (**common linearization**) (すなわち、ICD-10 の「一覧表」) が盛り込

まれている。死亡率報告では、記載どおりに共通線状化 (common linearization) を用いる必要がある。また、罹患率報告でも、詳細情報を提供するための拡張コードを使用できる。

2. 現在、共通線状化 (common linearization) は 24 章で示されている。(性障害 [Sexual Disorders] に関する新たな章を作成中である。また、血液学的疾患および免疫学的疾患を 2 つの異なる章に分けるかどうかについて、現在協議が行われている。) 共通線状化 (common linearization) は、死亡率と罹患率の両方に用いることを意図したものである。死亡率には用いられない章は、以下のとおりである：
  - a. 23 章の健康状態に影響を及ぼす要因および保健サービスの利用 (Factors influencing health status and contact with health services) (以前の「Z 章」)
  - b. 24 章の伝統医学における病態 [Traditional medicine conditions]
  - c. 6 章 (睡眠覚醒障害 [Sleep-wake disorders])。これは死亡率にとって特に重要ではない。
3. ICD-11 では、いくつかの変更が導入されており、**科学的知見の更新**が盛り込まれ、従来よりもコンピューター処理に適した分類となっている。このデザインには、新たな構造および一連の機能性の導入が必要であった。その結果、ICD-10 の一部の疾患単位 (entities) が、科学的により正確なカテゴリーによって置き換えられ、削除、改名、または再グループ化された。

## A. 一般的概念

1. ICD-11 のカテゴリー (共通線状化 [Common Linearization] における項目など) は、それらの分類特性を、ある一定の方法で配列することによって命名される—これを「**結合 (coordination)**」と呼ぶ。
2. 頻繁に使用される重要なカテゴリーの見出しには、あらゆる特性が統合されており、これを**事前結合 (precoordination)**と呼ぶ。このような事前結合コードは、**基幹コード (Stem Code)**と呼ばれる。
3. **事後結合法**によってさらに具体的な概念を作成するため、追加的な詳細情報を基幹コード (Stem Code) に追加することができる。事後結合には、許可された**拡張コード (Extension Code)**を用いて基幹コード (Stem Code) を拡張する体系的な結合が必要である。これらの拡張コード (extension code) は、多くの疾患に適用される一般的な特徴、たとえば、**重症度 (severity)**、**時間的特性 (temporal properties)**、**側性 (laterality)**などを意味する。これらは、**X 章のパラメータおよび値のセット**にまとめて記載されている。

4. **共通線状化 (Common Linearization)** において死亡率報告に用いられる ICD-11 のあらゆる概念は、**事前結合**されたものに限られる。ICD-11 では、死亡率の事前結合は、ICD-10 の 3 文字 (最高 4 文字) コードと同等のレベルで確立される。**罹患率**にとって重要な各概念の追加的な詳細情報を、事後結合において X 章を用いてコーディングすることができる。ただし、これは**死亡率**に用いるためのものではない。

a. **ICD-10 の 3 文字レベル**に相当する死亡率および罹患率項目 (すなわち *ICD-11 のコーディング・レベル 1*) は、相反する有力なエビデンスが存在しない限り、**事前結合**される。

**B50 熱帯熱マラリア (Plasmodium falciparum malaria) (ICD-10)**

=

**7P5 熱帯熱マラリア (Plasmodium falciparum malaria (ICD-11)**

b. **ICD-10 の 4 文字レベル**またはそれ以上に相当する罹患率項目 (すなわち *ICD-11 のコーディング・レベル 2*) および詳細情報のある項目は、相反する有力なエビデンスが存在しない限り、**主として事後結合**される (以下の赤字のテキストは事後結合される)。

**G00.0 インフルエンザ菌性髄膜炎 (Haemophilus meningitis) (ICD-10)**

=

**BC5.141 インフルエンザ菌による細菌性髄膜炎 (Bacterial meningitis due to Haemophilus influenza) (ICD-11)**

5. 事前結合と事後結合の相違を示すために、「**海岸線 (shoreline)**」という用語を用いる。(比喩的に言えば、事前結合は**陸地**を示し、事後結合は**海**を示す。) すべてを事前結合する必要がある**基幹コード (Stem Code)** の選択については、以下を考慮した**適用規則の一貫性**が必要である：

- a. 従来のコード (過去に死亡率の線状化[Mortality Linearization]で使用された場合)
- b. 科学的エビデンス
- c. 一貫性に関する分類学およびオントロジー的規則
- d. コーディングの実用性
- e. ある特定の線状化 (linearization) の診療環境における頻度
- f. 有用性
  - i. 臨床的
  - ii. 公衆衛生的

6. 頻繁に使用される重要な ICD-10 のカテゴリーをレビューした結果、以下のものが考案された：
- a. ICD-11 の 4 文字コード (約 2,225 カテゴリー)
    - 簡略死亡率一覧表 (SHORT Mortality List)
  - b. 一部の ICD-11 5 文字コード (約 6,353 カテゴリー)
    - 死亡率集計表線状化 (Mortality Tabulation Linearization)
  - c. すべての基幹コード (Stem Code) (約 15,000 カテゴリー)
    - 共通線状化 (common linearization)
7. 共通線状化 (common linearization) は、複数死因分析 (multiple cause of death analysis) が可能となるような詳細度に至るまで報告された死因をコーディングし、世界保健機関 (WHO) によって規定されたとおりに原死因 (underlying causes of death) の規則または選択を適用するために使用できる。
8. 一部の病態は、部位別に、あるいは病因別に体系化された場合などは、2 つの異なる場所に正しく分類される可能性がある。ICD-11 では、このような場合、関連する論理リンクを「親子関係化 (parenting)」と呼び、複数のリンクが存在する場合は、これを「複数親子関係化 (multiple parenting)」と呼ぶ。しかし、統計的計数の目的で一方の親のみが用いられる場合、これは「線状化親 (Linearization Parent)」として知られている。疾患単位 (entity) がどこかで親子関係化されるたびに、線状化親 (linearization parent) のコードが継続的に表示される。線状化親 (linearization parent) は、その線状化 (linearization) の「主要な親 (primary parent)」であると考えることができる。
9. 一般に、主要な親子関係 (primary parenthood) は、**病因**別に体系化される。したがって、感染症 (Infectious Diseases) と新生物 (Neoplasms) の 2 つの章が**首位 (primacy)**を与えられる。すべての感染症および新生物は、それら自身の章が主要な親とる。同様に、外因 (External Causes) にも首位 (primacy) が与えられている。ベータ段階におけるレビューの結果次第で、その他のセグメント、たとえば、発生異常 (Developmental Anomalies)、内分泌 (Endocrine)、または免疫疾患 (Immune disorders) もまた、同様にこのような状態となる。
10. 共通線状化 (Common Linearization) における ICD-11 の事前結合は、**基幹コード (STEM CODES)**によって頑健な共有構造を表すことを目的としている。罹患率報告を目的として、事後結合法により ICD-11 分類体系が幅広い表現度と詳細を備えたものとなる。事前結合された基幹コード (STEM CODES) は、事後結合される**拡張コード (EXTENSION CODES)**とともに使用できる (これらはすべて **X 章**にまとめられている)。ただし、すべての拡張コード (EXTENSION CODES) を任意の基幹コード (STEM CODES) と組み合わせてよいわけではない。基幹コード (stem code) に適用できる拡張コードは、認

可表 (SANCTIONING TABLES) に詳細に記述されている。認可表 (Sanctioning tables) は、関連する組み合わせ候補をそれぞれ適用可能 (Applicable)、必須 (Required) または適用不可 (Non-applicable) と判定する。また、認可表 (sanctioning tables) によって、事後結合法を用いて構築される可能性があるが事前結合されている概念も特定され、これによってユーザーは正確なコードに誘導され、重複を避けることができる。

- a. 適切な認可表 (sanctioning tables) を用いた事後結合法は、以下に適用できる：
  - i. 共通線状化 (Common Linearization) – WHO ICD-11 第 I 巻
  - ii. 各国の罹患率線状化 (National Morbidity Linearizations) – WHO ICD-11 の範囲を超えて拡張される国別の線状化 (linearizations)。(以下の 12 を参照)
  - iii. 特殊線状化 (Specialty Linearizations) (以下の 11 を参照)

11. 事後結合できないが、詳細情報が多すぎて共通線状化 (Common Linearization) に含まれない疾患単位 (Entities) は、引き続き、索引および包含語 (inclusion term) として表示される。また、これらの疾患単位 (entities) は、特殊線状化 (Specialty Linearizations) または各国の線状化 (National Linearization) において、希望する場合は、基幹コード (stem codes) とすることも可能である。

12. 各国の罹患率線状化 (National Morbidity Linearizations) : 各国による ICD の使用にあたっては、WHO の国際的罹患率線状化 (International Morbidity Linearization) の共通項で表されている以上に詳細が求められると考えられる。このことは、過去に、ICD-10 AM (オーストラリア)、CM (アメリカ)、GM (ドイツ)、CA (カナダ) といった国別の改訂 (National Modifications) によって証明されている。ICD-11 の事後結合法は、こうした詳細の拡張を可能にする一方で、非標準的な改変を制限する。

- a. 各国の罹患率線状化 (National Morbidity Linearizations) を続行することを希望する国は、続行のためのライセンスを付与される。これには、各国の罹患率線状化 (National Morbidity Linearization) 開発者が追加項目をすべて基本コンポーネント (Foundation Component) に追加して、それらをどのように親子関係化すべきか、また線状化すべきかを明らかにすることが必要である。WHO は、その基盤とツールを提供していく。ICD-11 および ICD-10 の各国臨床修正 (National Clinical Modifications) 間の安定性解析によって、WHO の ICD-11 と、各国の罹患率線状化 (national morbidity linearizations) との一致を確認する。
- b. さまざまな各国の罹患率線状化 (national morbidity linearizations) 間の同等性は、ICD-11 の基本・線状化コンポーネント (Foundation-Linearization Components) 全体にわたって維持されるであろうと考えられている。このようにして、各国の罹患率線状化 (National Morbidity Linearizations) による追加的な詳細情報の一部は、国際的

罹患率線状化 (International Morbidity Linearization) の持続的改善に役立つと考えられる。

13. 特殊線状化 (**Specialty Linearizations**) : 特殊医療には、しばしば共通線状化 (Common Linearization) を超えたさらなる特異化が必要となる場合がある。特殊線状化 (Specialty Linearizations) (以前は「特殊適応 (Specialty Adaptation)」と呼ばれていた) を定式化するには2つの方法がある:
- 罹患率線状化 (Morbidity Linearization) のさらなる拡張として (たとえば、過去には、*神経科 (Neurology)* の適応で ICD コードにさらに桁を追加して拡張したものが使用されており、*精神衛生 (Mental Health)*、*口腔衛生 (Oral Health)* などにおいても同様のその他の特殊適応が行われていた)。その他の ICD-11 の特殊線状化 (Specialty Linearizations) としては、以下のようなものがある: *皮膚科 (Dermatology)*、*眼科 (Ophthalmology)*、*妊娠と生殖に関する健康 (Reproductive Health)* (*泌尿生殖器・生殖医学 [GURM]*)、*伝統医学 (Traditional Medicine)*、*外因および傷害 (External Causes and Injury)*、*希少疾患 (Rare Diseases)* など。*睡眠および疼痛 (Sleep and Pain)* には独自の特殊線状化 (Specialty Linearizations) がある可能性があり、その他にも特定される可能性がある。
  - ICD-11 の研究線状化 (Research Linearizations)** — これらの線状化は、基本コンポーネント (Foundation Component) から新たに直接作成された。これらはしばしば分類領域全体ではなく、特殊分野を示す。このような場合、特殊線状化 (Specialty Linearizations) は、必ずしも共通線状化 (common linearization tree) のツリーを死亡率および罹患率線状化 (Mortality and Morbidity Linearizations) と共有せず、むしろ、ICD から異なる方法でグループを再編成すると考えられる。同等性が保たれるように、基本層 (Foundation Layer) によって、これらのバージョンの一致が図られる。

いずれの定式においても、特殊線状化 (Specialty Linearizations) における追加的な疾患単位 (entities) は、主要部をなす ICD-11 と完全な互換性がなければならず、データの同等性を目的として概念を追跡することを可能にする識別情報を持つ。

14. 同じ概念を複数の方法で表すことを避けるため、認可表 (sanctioning tables) を作成し、これによって正確な疾患単位 (entity) の選択を支援する。これらの認可規則は、当初は共通線状化 (Common Linearization) のために策定されたものであったが、特殊線状化 (Specialty Linearizations) にも適用される。

15. 共通線状化 (Common Linearization) に重要ではないと考えられる追加的な詳細情報は、特殊線状化 (Specialty Linearizations) において示すべきである。すべての詳細化された特殊線状化 (Specialty Linearizations) の子について、共通線状化 (Common Linearization) に親が存在する。このような追加カテゴリーは、ICD-11 の国際的罹患率線状化 (International Morbidity Linearization) の関連する箇所において、包含語および索引項目とする必要がある。

## 16. ICD 11 の残余カテゴリー

- a. 分類線状化は、2 つの基本ルールに従う必要がある：
- そのカテゴリーは相互排他的 (Mutually Exclusive) でなければならない
  - そのカテゴリーは連結によって網羅的 (Jointly Exhaustive) となければならない
- b. これらのルールに従うには、分類線状化の各セグメントに 2 つの残余カテゴリーを含める必要がある
- 上記のクラスに含まれていないもの
  - 特定化されていないもの
- c. ICD の残余コードには、従来から以下の 2 種類がある：

### \*.8 – その他 (に特定される) (Other (specified))

(意味的には、他に分類されない [Not Elsewhere Classified: NEC] とほぼ同等)

### \*.9 – 詳細不明 (Unspecified)

(意味的には、他に特定されない [Not Otherwise Specified: NOS] とほぼ同等)

ICD-11 の線状化 (Linearizations) においても、これらの規則を、ICD-11 線状化 (Linearizations) コードを用いた以下の形式で継続することが提案されている：

その他に特定される (Other Specified) の終了文字 **\*Y**

詳細不明 (Unspecified) の終了文字 **\*Z**

この規則は、実際に視認できることを目的として用いる。

ICD-11 の基本コンポーネント (Foundation Component) の場合、各 ICD-11 カテゴリーには独自の個々のスペースと一覧表がある。残余カテゴリーは、



基本コンポーネント (Foundation Component) には発生しない。それらはコンピュータ・アルゴリズムによって自動的に生成される。

## 24 章—伝統医学における病態—モジュール I

### 章の構成および階層の概要

この新たな章は、伝統医学の保健医療や外来診察の意義を高めること、また、それらが国家的・国際的に重視されることを目標として作成された。本章では、その現行形式 (モジュール 1) において、中国、日本、韓国、およびその他世界各国で一般的に用いられている古代中国医学に起源を持つ障害およびパターンに言及している。分類項目は、中国、日本および韓国の国別分類に基づく、統合された、伝統医学における一連の統一疾患およびパターンを表している。

本章は 2 部に分かれている。第 1 部では、伝統医学における疾患を 15 のセクションに分類している：

### 伝統医学における疾患 (TM)

1. 心臓系障害 (Heart system disorders) (TM)
2. 肺系障害 (Lung system disorders) (TM)
3. 脾臓系障害 (spleen system disorders) (TM)
4. 肝臓系障害 (Liver system disorders) (TM)
5. 腎臓系障害 (Kidney system disorders) (TM)
6. 脳系障害 (Brain system disorders) (TM)
7. 精神および情動系障害 (Mental and emotional disorders) (TM)
8. 眼、耳、鼻および咽喉系障害 (Eye, ear, nose and throat system disorders) (TM)
9. 骨、関節および筋肉系障害 (Bone, joint and muscle system disorders) (TM)
10. 皮膚および粘膜系障害 (Skin and mucosa system disorders) (TM)
11. 気、血および水 (津液) の障害 (Qi, blood and fluid disorders) (TM)
12. 外感病 (External contraction disorders) (TM)
13. 女性生殖器系障害 (Female reproductive system disorders) (TM) (出産を含む)
  - a. 月経関連障害 (Menstruation associated disorders) (TM)
  - b. 妊娠関連障害 (Pregnancy associated disorders) (TM)
  - c. 産褥関連障害 (Puerperium associated disorders) (TM)
  - d. その他の女性生殖器系関連障害 (Other female reproductive system associated disorders) (TM)
14. 小児期および青少年期関連障害 (Childhood and adolescence associated disorders) (TM)
15. ある種の特定障害 (Certain specified disorders) (TM)

第2部では、伝統医学におけるパターンを10のセクションに分類している：

### 伝統医学におけるパターン (TM)

1. 原理に基づくパターン (Principle-based patterns) (TM)
2. 人体構成要素のパターン (Body constituents patterns) (TM)
  - a. 気のパターン (Qi patterns) (TM)
  - b. 血のパターン (Blood pattern) (TM)
  - c. 水 (津液) のパターン (Fluid patterns) (TM)
  - d. 精のパターン (Essence patterns) (TM)
3. 器官系パターン (Organ system patterns) (TM)
  - a. 肝臓系パターン (Liver patterns) (TM)
  - b. 心臓系パターン (Heart patterns) (TM)
  - c. 脾臓系パターン (Spleen patterns) (TM)
  - d. 肺系パターン (Lung patterns) (TM)
  - e. 腎臓系パターン (Kidney patterns) (TM)
4. 環境要因のパターン (Environmental factor patterns) (TM)
5. 経絡のパターン (Meridian patterns) (TM)
  - a. 正経のパターン (Main meridian patterns)
  - b. 奇経のパターン (Extra meridian patterns)
6. 六病位のパターン (Six stage Patterns) (TM)
  - a. 太陽病期のパターン (Early yang stage patterns) (TM)
  - b. 少陽病期のパターン (Middle yang stage patterns) (TM)
  - c. 陽明病期のパターン (Late yang stage patterns) (TM)
  - d. 太陰病期のパターン (Early yin stage patterns) (TM)
  - e. 少陰病期のパターン (Middle yin stage patterns) (TM)
  - f. 厥陰病期のパターン (Late yin stage patterns) (TM)
7. 三焦病位のパターン (TM)
  - a. 上焦のパターン (Upper energizer stage patterns) (TM)
  - b. 中焦のパターン (Middle energizer stage patterns) (TM)
  - c. 下焦のパターン (Lower energizer patterns) (TM)
  - d. 混合焦のパターン (Mixed energizer patterns) (TM)
8. 4証のパターン (TM)
  - a. 衛分証のパターン (Defense phase patterns) (TM)
  - b. 気分証のパターン (Qi phase patterns) (TM)
  - c. 営分証のパターン (Nutrient phase patterns) (TM)
  - d. 血分証のパターン (Blood phase patterns) (TM)
9. 四象医学のパターン Four constitution medicine patterns (TM)
  - a. 太陽人型のパターン (Large yang type patterns) (TM)
  - b. 少陽人型のパターン (Small yang type patterns) (TM)
  - c. 太陰人型のパターン (Large yin type patterns) (TM)
  - d. 少陰人型のパターン (Small yin type patterns) (TM)
10. 処方パターン (Formula-Patterns) (TM)

### Ⅲ. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

書籍

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## Review Article

# Pattern Classification in Kampo Medicine

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Pattern classification is very unique in traditional medicine. Kampo medical patterns have transformed over time during Japan's history. In the 17th to 18th centuries, Japanese doctors advocated elimination of the Ming medical theory and followed the basic concepts put forth by Shang Han Lun and Jin Gui Yao Lue in the later Han dynasty (25–220 AD). The physician Todo Yoshimasu (1702–1773) emphasized that an appropriate treatment could be administered if a set of patterns could be identified. This principle is still referred to as “matching of pattern and formula” and is the basic concept underlying Kampo medicine today. In 1868, the Meiji restoration occurred, and the new government changed its policies to follow that of the European countries, adopting only Western medicine. Physicians trained in Western medicine played an important role in the revival of Kampo medicine, modernizing Kampo patterns to avoid confusion with Western biomedical terminology. In order to understand the Japanese version of traditional disorders and patterns, background information on the history of Kampo and its role in the current health care system in Japan is important. In this paper we overviewed the formation of Kampo patterns.

## 1. Introduction

The globalization of health care has not left traditional medicine behind. The World Health Organization (WHO) took the initiative for globalization of traditional medicine by founding the Division of Traditional Medicine in 1972 [1]. In 1978, the Alma-Ata Declaration on Primary Health Care called on countries and governments to include the practice of traditional medicine in their primary health care approach [2]. Thirty years later, traditional medicine is widely available, affordable, and commonly used in many parts of the world.

WHO is presently updating its International Classification of Diseases from the 10th (ICD-10) to 11th edition (ICD-11) [3, 4] and plans to incorporate traditional medicine into this new version. International experts from China, Korea, Japan, Australia, the US, and the EU are involved in this project. The ICD-11 alpha version was released in 2011, and the beta version was released in May 2012, with a version also available on the web [5].

The ICD-11 beta version contains 2 sections on traditional medicine: “traditional disorders” and “patterns” (zheng in

Chinese). China and Korea referred to their own national standards to develop these sections. China used the 1995 classification and codes of traditional disorders and patterns of traditional Chinese medicine (GB95) as a national standard. The third edition of the Korean Classification of Diseases of Oriental Medicine (KCDOM3) was incorporated into the Korean modification of ICD-10 (KCD-6) in 2010. KCD-6 was groundbreaking because it was the first publication in which Western biomedicine and traditional medicine shared a common platform in terms of medical statistics.

For Japan's contribution to this edition, the Committee for Terminology and Classification of the Japan Society for Oriental Medicine (JSOM) was responsible for organizing the section on Kampo classification. Kampo covers a wide variety of traditional Japanese medicine including acupuncture and moxibustion, existing before Western medicine was introduced to Japan. In contrast to China and Korea, Japan did not have national standards for reference. To understand the Japanese version of traditional disorders and patterns, background information on the history of Kampo and its role in the current health care system in Japan is important.

## 2. History of Kampo Medicine

Medicines were brought from ancient China to Japan via the Korean peninsula in the 5th or 6th century. While Japanese medicine originally followed the ways of ancient Chinese medicine, Japan adopted Chinese knowledge to suit its own climate and race [6]. Also because not all materials were available, Japan replaced the material to the Japanese herbs and minerals. The first Japanese medical book, “Daidoruijuho,” was a collection of Japanese traditional therapies written in 808.

Further modifications of Japanese traditional medicine occurred during the Edo period (1603–1867) [7, 8]. The medicine of Ming-China was introduced at the beginning of this period and spread widely (Gosei school). During this time, Japanese doctors advocated the elimination of Ming Chinese medicine, instead following the basic concepts of Shang Han Lun and Jin Gui Yao Lue introduced during the later Han dynasty (25–220 AD). The physician Todo Yoshimasu promoted his perspective on these classic texts and rejected the theory developed later in China. His approach emphasized that an appropriate treatment could be administered if a set pattern could be identified, a practice still referred to today as “matching of pattern and formula” (Koho school). Later in the Edo period, another school which integrated both Koho style and Gosei style occurred (Setchu school).

Among these three schools, Koho school influenced most the current Kampo practice in Japan.

In the 18th century, European medicine was introduced in Japan. Modern anatomy was first studied in 1754 by Toyo Yamawaki, a famous Kampo doctor who had acquired an anatomy book from Europe. Toyo Yamawaki respected Yoshimasu, who also knew European medicine. Yoshimasu may have tried to reform Kampo medicine to harmonize it with European medicine.

This trend was followed by other doctors like Seishu Hanaoka (1761–1835), who performed the first surgery with general anesthesia in 1804. This event occurred 42 years before William T. G. Morton successfully performed surgery using ether as a general anesthetic. Hanaoka combined Kampo and European medicines, using Kampo mainly for internal medicine and European medicine for surgery.

The Meiji restoration occurred in 1868, and the new government decided to modernize Japan introducing European culture including medicine. With the passing of the 1874 Medical Care Law, the German model was adopted as the national health care system, and all Kampo-related systematic education was stopped. Kampo practitioners were no longer recognized as official medical professionals; for those interested in becoming physicians, the only option available was to study Western medicine and pass a national examination. Thereafter, the practice of Kampo drastically declined.

After difficult years, physicians like Kyushin Yumoto (1876–1941), Keisetsu Otsuka (1900–1980), and Domei Yakazu (1905–2002) played a key role in reviving Kampo medicine. For Kampo medicine to survive, these physicians had to transform it into a more practical form that the new

generation of physicians would also find useful. The modern form of Kampo medicine lost much of its theoretical origin, and emphasis was now being placed on proper prescription of Kampo formulas for treating symptoms. These changes made Kampo conceptually easier to understand for the new generation of physicians trained only with Western medicine. Moreover, the “matching of pattern and formula” methodology made the clinical use of Kampo a more appealing form of treatment.

The result of these efforts was that, by 1967, the first 4 Kampo formulas were approved by the government for coverage under the national insurance system.

## 3. Current Status of Kampo Medicine in Japan

Recent research shows that about 90% of physicians in Japan use Kampo medicines in daily practice, even for cancer patients [9–11]. For women’s health, nearly 100% of Japanese obstetrics/gynecology doctors use Kampo medicine [12–14]. Physicians even use Kampo medicine in the university hospital along with high-tech techniques such as organ transplantation or robotic surgery. Physicians often use Kampo medicines along with chemotherapy or radiation therapy for cancer patients. These examples show the magnificent integration of modern Western biomedicine and traditional medicine [15, 16].

Kampo medicine has government-regulated prescription drugs, and now 148 formulas are listed on the Japanese Insurance Program. Kampo practitioners can also use decoctions, selecting several herbs among 243 types covered by the insurance system [17]. In 2001, the Ministry of Education, Culture, Sports, Science and Technology decided to incorporate Kampo medical education into the core curriculum of medical schools. There are 80 medical schools in Japan, all of which now provide Kampo medical education.

## 4. How the “Kampo Medical Classification” Developed Recently in Japan

The Japan Society for Oriental Medicine (JSOM) was founded in 1950 and is the largest academic association for Kampo medicine. The JSOM Committee for Terminology and Classification decided not to use traditional names for disorders in Kampo classification because many of them overlap with Western biomedical terms. Traditional names for disorders are primarily symptoms, such as “headache” or “watery diarrhea.” In contrast, in Western medicine, disease names are based on pathological causes, such as cholera or malaria. Since these diseases have existed for a long time, traditional medicine recognizes these diseases. However, the pathologies of these diseases were unknown when the names were given and so are not reflected in the disease names in traditional medicine. Therefore, it is difficult to map traditional disorder names and biomedical disease names. Sometimes, symptomatic traditional names for disorders are broad and can be mapped to multiple biomedical disease names. Because the restoration of Kampo medicine in Japan was led by physicians, Western

biomedical terms were often used instead of the traditional Kampo terms to avoid confusion.

Organ system patterns are very important in medicine in China and Korea. However, Kampo experts in the Meiji (1868–1912), Taisho (1912–1925), and Showa (1926–1989) eras chose not to use organ systems to avoid overlap with biomedical terms. As a result, Kampo medicine is sometimes criticized because of the relative lack of terms to describe patients' conditions. The pathogenesis rather than host reaction is most important in Western biomedicine. In contrast, the host's reaction to the pathogen is the most important factor in traditional medicine. In this regard, Kampo medicine has been developed in harmony with Western biomedicine.

## 5. Kampo Medicine Patterns

Kampo patterns were reconstructed logically according to the ICD principles, which are both jointly exhaustive and mutually exclusive. Several parameters are used for determining Kampo patterns: yin-yang, deficiency-excess, cold-heat, 6 stages of acute febrile diseases, and qi-blood-fluid [18]. Of these, yin-yang, deficiency-excess, cold-heat, and interior-exterior belong to the 8 principles used in Chinese medicine. In China, each component is used in combination with the others to define the pattern, such as “liver yin deficiency pattern,” and is not usually used independently. Among 8 principles, yin-yang is a polysemic word. Sometimes it is used for the sensible temperature in Japan. Under international harmonization, yin-yang is usually a high-level concept of deficiency-excess, cold-heat, and interior-exterior. To avoid confusion, we decided not to use yin-yang for the sensible temperature.

Kampo patterns are determined for all patients according to the flow charts shown in Table 1 and Figure 1. Patient conditions are divided into 2 groups: acute febrile infectious conditions and chronic conditions (Figure 1). A 6-stage pattern, based on Shang Han Lun, is used for describing acute febrile infectious diseases like influenza. Qi-blood-fluid patterns are mainly used for describing chronic diseases.

One issue raised regarding Kampo patterns concerns the “between deficiency and excess” pattern. The deficiency and excess pattern is usually based on the strength of the pathogen. However, in Japan, deficiency and excess patterns are primarily based on the patient's condition. The ancient textbook of Huangdi Neijing (Former Han dynasty; 220 AD to 8 AD) explains that “when the foreign pathogen is strong, it is called as excess, and when body energy is weakened, it is called as deficiency.” The problem with this statement is that deficiency is defined by the strength of foreign pathogens, and deficiency is defined by the energy of the host. Many traditional medical terms are polysemic, mainly due to their long history. However, the deficiency-excess terms are originally polysemic; this has created much confusion.

In Japan, deficiency-excess was originally determined by the strength of the foreign pathogen in the case of acute febrile infectious diseases and by the strength of the body energy in the case of chronic diseases. Additionally, Kampo medicine

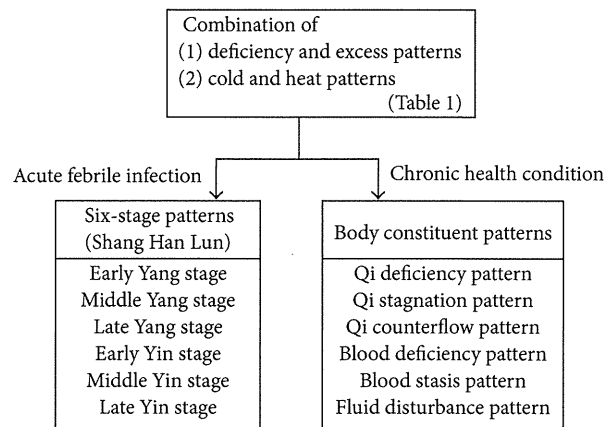


FIGURE 1: Diagnostic flow used in Kampo medicine. All patients are assigned a specific category as described in Table 1 and then divided into 2 groups according to whether they have acute febrile infectious disease or chronic disease. For acute febrile disease, the 6 stages of Shang Han Lun are very important. For chronic diseases, the host body constituent patterns are very important.

was used extensively for acute febrile infectious diseases before antibiotics were developed, where the strength of the foreign pathogen was very important. Since the development of antibiotics, Kampo medicine has been used more often for chronic diseases, in which the strength of the body energy is more important. In the modern version of Kampo, the host condition is assigned a high value, while the foreign pathogen is addressed by Western biomedicine. Therefore, the host energy is of greater importance. The need thus arose for the option to designate the body energy level as “neutral” rather than just “deficient” or “excessive.” This issue was raised by Tokaku Wada (1743–1803), a physician in the Edo period [19]. His clinical wisdom was described in “Dosui Sagen” which was published in 1805. In this book, “between deficiency and excess” was described in the type of edema. This idea is thought to have influenced Kazuo Tatsuno (1905–1976) [20, 21] and other physicians in the Showa era. For example, a patient with impaired glucose tolerance appears normal according to the older Kampo designations, even though Kampo medicine is indicated for this condition. In such cases, the “neutral” designation enables acknowledgment of a condition that lies between deficiency and excess.

## 6. Formula Pattern

The formula pattern is also very unique in Kampo medicine. While traditional Chinese medicine (TCM) prescriptions are individualized at the herbal level, Kampo medicine is individualized at the formula level. This practice may have started during the Edo period, as usage of different amounts of herbs was described in a book by Kaibara in 1712 [22]. According to this book, the amount of each herb used in Japan was 1/5 to 1/3 that used in China. Kaibara explained that one of the reasons for this practice was the difficulty in importing herbs from China. Even though alternative herbs available in Japan were used, some had to be imported from

TABLE 1: Combinations of deficiency-excess and cold-heat patterns.

Components	Cold	Heat	Between cold and heat	Tangled cold and heat
Deficiency	Cold, deficiency	Heat, deficiency	Between cold and heat, deficiency	Tangled cold and heat, deficiency
Excess	Cold, excess	Heat, excess	Between cold and heat, excess	Tangled cold and heat, excess
Between deficiency and excess	Cold, between deficiency and excess	Heat, between deficiency and excess	Between cold and heat, between deficiency and excess	Tangled cold and heat, between deficiency and excess

Regardless of acute or chronic health conditions, all patients are classified into 1 of these 12 combinations. Very limited combinations are used for acute diseases. Between deficiency and excess; neutral in "deficiency and excess"; between cold and heat; neutral in "cold and heat"; tangled cold and heat; mixture "cold and heat," for example, cold foot and hot flush on face.

China. These differences in the amounts of herbs used are still prevalent. This may explain why Kampo medicine is individualized at the formula level. During the Edo period, doctors carefully studied the roles of formulas and decided the characteristics of each formula. This practice led to Yoshimasu's idea of "matching of pattern and formula."

Physicians continue to follow this principle today. Clinical trials have been conducted using the same Kampo formula used previously for a specific disease, determining the appropriate Kampo formula based on host patterns. "Matching of pattern and formula" has thus been shown to be a sophisticated approach.

By 1967, the first 4 Kampo formulas were approved by the government for coverage under the national insurance system, and 148 are now listed.

The acceptance of Kampo formulas into the national health insurance system marked the start of the exponential growth of Japan's market in Kampo medicines. Between 1976 and 1992, the sales of Kampo medicine grew more than 10-fold in Japan (Japan Kampo Medicine Manufacturers Association, 2007) [23].

With such a rapid increase in the number of Kampo drug products sold, the government and pharmaceutical industry needed to ensure that high standards were maintained. In 1987, the government established the Good Manufacturing Practice (GMP) law to ensure safety in manufacturing processes, including the production of Kampo formulas. The stringent manufacturing process for Kampo medicine has increased the legitimacy of this modality, as people can now expect uniformity and high quality from the different formulas. This facilitates "matching of pattern and formula," because if the formulas are not stable, it is very difficult to consistently match pattern to formula.

## 7. Future Challenges

Even though all 80 medical schools in Japan have incorporated Kampo medical courses into their curricula, the number of such courses is very small compared to that of Western biomedicine courses. Postgraduate and continuous Kampo medical education have not been established. Statistics indicate that Kampo formulas are used in daily practice by 90% of physicians, which represents over 260,000 physicians. However, the number of Kampo experts certified by the JSOM is only 2150. This great discrepancy means

that most physicians use Kampo formulas based on Western biomedical disease diagnoses without deep consideration of patterns. Further education is necessary for the users of Kampo formulas.

Another concern for the future is the coding rule used for the qi-blood-fluid pattern. Deficiency, excess, and between deficiency and excess are mutually exclusive. Likewise, cold-heat and the 6 stages are mutually exclusive in the same category. However, several abnormalities in qi-blood-fluid may exist in 1 patient. We conducted a small clinical trial without establishing any coding rules. Some doctors provided only 1 code for the qi-blood-fluid pattern, while others provided 4 codes. For more accurate statistics, coding rules should be developed and training in coding should be imparted.

In terms of international comparisons, Kampo patterns are too simple compared to TCM and traditional Korean medicine (TKM). Organ system patterns are particularly lacking in Japan. However, in ICD-11, all the patterns will be presented on the common platform of Western biomedicine. Some organ system patterns can be linked to Western biomedicine disease codes, even though they do not map one-to-one. ICD 11 has terminology that is novel to ICD. This allows ontology software precisely describe the content of each term and links the different codes to each other. The next stage of ICTM development will be field testing. We expect that the international field test will allow for international comparisons.

## 8. Conclusion

Kampo patterns are rather unique compared to Chinese or Korean patterns. There are 2 explanations for this difference. First, Kampo medicine was separated from the theory of the Ming dynasty and then reestablished based on Shang Han Lun theory during the Edo period. Second, Kampo medicine is used in combination with Western biomedicine by licensed doctors in Japan. Kampo terminology was redeveloped in order to avoid confusion with Western biomedicine.

## Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

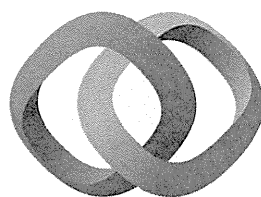
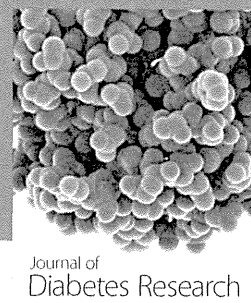
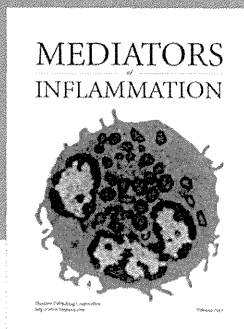
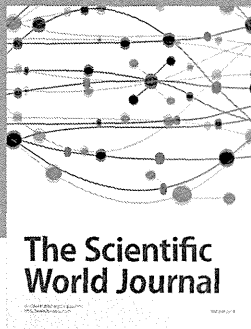


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