The role of Western Medicine in Integrated Chinese-Western Medicine in stroke care

Dr. Kevin OR
Convener, ICWM Clinical WG on Stroke Care, HA.
Consultant Geriatrician, Dept of M & G, Shatin Hospital.
Registered CMP
20140905

ACKNOWLEDGEMENT & POSITIONING

Acknowledgement

- 中醫中藥發展委員會 中醫業小組委員會
- Task Force on the Development of Integrated Western and Chinese Medicine, Hospital Authority
- Operational Working Group on ICWM pilots
- Clinical Working Group on ICWM stroke care
- Chinese Medicine Department, Hospital Authority
- Chief Pharmacy Office, and Expert Panel on Herbal Formulary in ICWM Pilots, Hospital Authority
- Project-related HA staffs and hospital clusters of KWH, PWH, SH, TWH, and WTSH.

Development of Integrated Chinese-Western Medicine (ICWM) 中西醫協作項目

Policy Address 2013
"promoting treatment with integrated Chinese and Western Medicine;…introducing CM in-patient services."

CM Development Committee (March 2013)
" explore means to facilitate the collaboration of CM & WM practitioners & expand the role of CM in the public healthcare system." " study the feasibility of establishing a CM hospital"

Endorsement of the Framework for the Development of ICWM
via Ds' Meeting (25 Sep 13), MSDC (25 Nov 13) and AOM (19 Dec 13)

Establishment of Task Force
Positioning & implementation plan for the development of ICWM discussed in
1st (3 Dec 13), 2nd (27 Jan 14), 3rd (26 Mar 14) and 4th Meeting (3 Jun 14)

Clinical Working Groups
Protocol development
- 3-4 rounds of meetings held from Dec 13 to date

Operational Working Group
Guidelines development on
- Financial arrangement
- Incident management
- CM Prescribing, Dispensing & Administration
- CM Nursing Care
- Medical Record Handling

Programme Positioning

- HA shall set up the framework & organize the ICWM service
- CM component of the ICWM care is NOT part of the highly subsidized public healthcare services
- Patients will receive the ICWM service on voluntary basis & pay a fee on the CM component
- The ICWM service will consist of the following parts:
  - WM care to be provided by HA as part of the standard highly subsidised public healthcare service
  - CM care to be organised by HA but provided by an external service provider, i.e. NGO under tripartite arrangement (CMCTR)
  - Academic expertise input and support from universities as appropriate in the tripartite model

Patient-centered public hospital system - A Personal View

- Shortfalls of the current public hospital system
  - thousands of beds
  - hundreds of doctors……
- Nearly seven thousands of registered Chinese medicine practitioners
  - ?public hospital role of CMP
  - ?role of the proposed CM hospital

OPERATIONAL FRAMEWORK

CM hospital service under HK laws

- Insert a specialty into WM hospital in less than a year

>> *Operational (Administrative) Framework*

(a) Objectives & Scope

1. to examine for the feasibility of providing in-patient Chinese medicine (CM) services in selected public hospitals;
2. and to train staffs for the future CM hospital in Hong Kong.

- Based on prior experience at Hospital Authority (HA), three areas of inpatient care - stroke, cancer palliative, and low back pain, have been selected.

(b) Dual Framework

Aim to guide the development of an IWCM model
via piloting IWCM programmes in HA hospitals.

Framework for IWCM development

Explore feasibility and gain
experience via small-scale pilots

Proposed disease-based projects

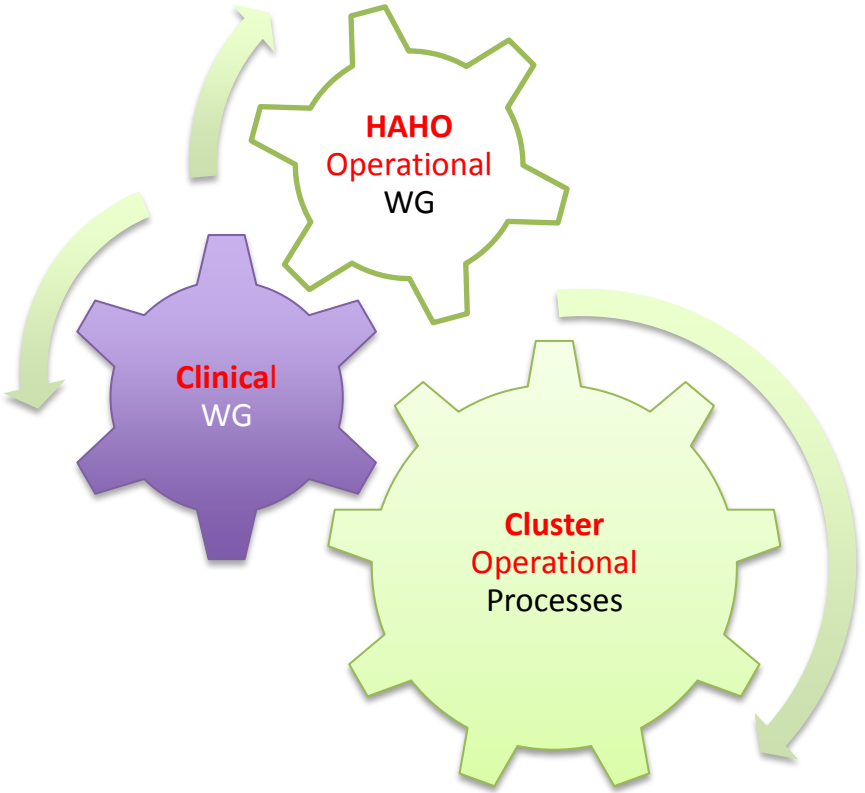
- Stroke rehabilitation
- Cancer palliative care
- Musculoskeletal pain management

Evaluate & consolidate

IM-Stroke Pilot: a Service Feasibility Project

Project Layers

Organizer Interactions



IM-Stroke Pilot: HO-Cluster Stakeholder Tasks Table

HAHO	*Tasks-to-Date*	Cluster / NGO
Taskforce	*Project steering*	CMC
BSS	*NGO service contracts*	NGO
LSD / Finance	*HA-NGO legal positions & insurance policies*	
FD	*Funding allocation, patient payment guideline*	FD
CMD	*Funding Coordination*	ICWM
CMD	*Operation Manual & Informed Consent*	ICWM
IM Stroke WG	*Clinical Protocol*	Clinical Dept & NGO
CMD	*Staff Engagement*	ICWM
CMD	*Training to WM staffs*	ICWM / iLearn
CMD	*Training to CMP's*	NGO
HR	*HA project staffs & NGO CMP's*	HR
HI&RS	*CM documentation & filing guidelines*	HI&RS / Nursing
ITS	*Inpatient label, CMIS dataport, office IT*	ITS
Nursing	*Herbal administration guideline*	Nursing/Med Safety
CPO	*Herbal delivery, CM-MAR*	Pharmacy
EP	*Herb-Drug Interaction & Herbal Toxicity*	Clinical Dept & NGO
CMD	*Acupuncture Guideline*	Procedural Safety
CMD	*Introduce technologies new to HA / Cluster*	Technology
CMD	*Label & maintain CM elect. & engine. equipments*	?E&M / NGO
Allied Health	*Avoid service duplication & scheduling conflicts*	Allied Health
CMD	*Prepare site office*	Facility Mx
CMD	*Provide project office F&E*	Procurement & MMS
Q&S	*Mechanism to communicate with AIRS, SE/SUE*	Q&S
Nursing(APN)	*Clinical Audit*	Clinical Dept & NGO
PRO	*Mechanism to handle complaints*	PRO
Corp. Com	*HA-cluster image & public enquiries*	Comm & CR
	New staff orientation program	Patient Privacy
	New staff orientation program	Infection Control
	New staff orientation program	OSH & Fire Safety

病房工作流程

醫院管理局中西醫協作先導計劃-中風治療:
病人須知

1. 計劃簡介
- 醫院管理局(醫管局)透過與三方協作中醫教研中心(中醫教研中心)合作,為醫管局病人推出本次中西醫協作先導計劃。
- 此計劃將根據中醫及西醫專家組成的工作小組所訂下的臨床方案,安排中醫教研中心的註冊中醫師(中醫師)提供中醫治療服務。
- 在合適的情況下,亦會根據臨床方案安排病人在指定的中醫教研中心覆診並跟進病情。

3. 費用及付款方式
4. 中醫治療風險及注意事項
5. 條款及細節

2. 治療簡介

a) 主診西醫/專責護士將會根據臨床方案邀請適合的病人參與中西醫協作先導計劃。

b) 中醫教研中心的中醫師會每日到指定病房為參與計劃病人診症,根據臨床方案及臨床判斷為病人提供適切的中藥或針灸治療。

c) 中醫師只會為住院病人處方中藥顆粒。為減低中藥及西藥產生相互作用的潛在風險,病人必須嚴格遵守醫護人員所指示的服藥劑量、次數及時間。如有疑問應隨時向醫護人員查詢。

d) 病人出院之後,主診醫生及中醫師將會共同決定病人是否需要門診跟進病情。根據臨床方案病人可能會被安排於指定中醫教研中心接受中藥或針灸治療。

醫院管理局中西醫協作先導計劃 -中風治療:

表格 (病房工作流程)

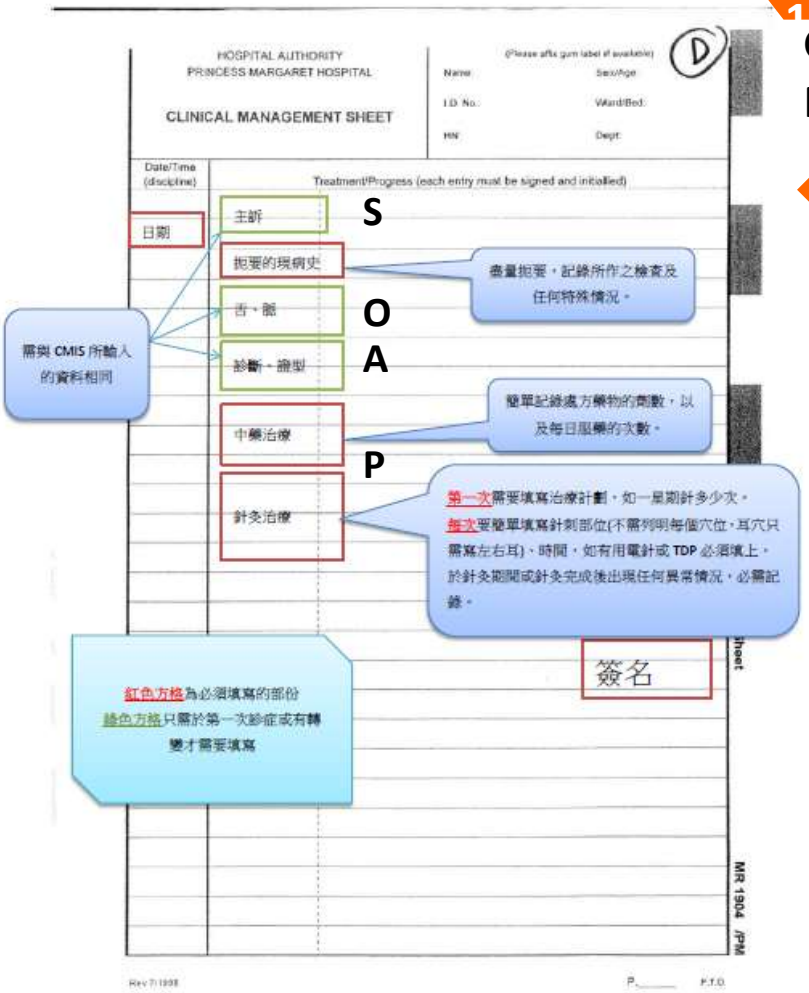
A. 參加表格 Enrolment Form
B. 病人須知 Notice to Patient
C. 接受中醫治療同意書 Consent for Chinese Medicine Treatment
D. 病人名單 (中醫評估) Patient List (for CMP Assessment)
E. 參加者名單 (由病房填寫) Enrolment List
F. 第一次預約名單 First Appointment List
G. 預約日程報表
H. 針灸初診評估, 針灸治療記錄表
I. 每日出院 / 退出計劃名單 Daily Discharge / Exit Program List
J. 出院總結

Guidelines on Chinese Medicinal Nursing

- Nursing administration of Chinese medicines:
  - Flowchart to collect and check the Chinese medicines dispatched from CM center by ward nurse
  - Forms:
    - 中醫處方箋 (配方顆粒);
    - 住院病人給口服中藥紀錄 (CM-MAR)
    - 中藥派送確認簽收表
    - 補發, 更換中藥表格
  - Labels:
    - 醫院住院病人標籤 (Hospital in-patient barcode gum label);
    - 求診人條碼標籤 (CM patient barcode label);
    - 中醫中心病人標籤-ICWM (CM patient Gum label -ICWM);
    - 中醫中心病人中藥標籤-ICWM (CM patient drug label -ICWM);
    - 求診人條碼標籤 (CM patient barcode label);
    - 配藥記錄標籤 (CM dispensing record label)
- Acupuncture guideline
  - Form: 針灸治療紀录表

RECORD MANAGEMENT

Documentation of CM Progress Notes



1. Guidelines for CMP to document on Integrated Patient Documentation (IPD)

2. Cross-reference in CMIS record

Filing of CM related Record

- List of documents to be filed in HA
  - Patient Enrolment Form
  - CM Consent Form
  - Acupuncture Checklist
  - CM Discharge Summary
  - CM-MAR
- HA document numbers have been assigned and shall follow existing filing system of HA.

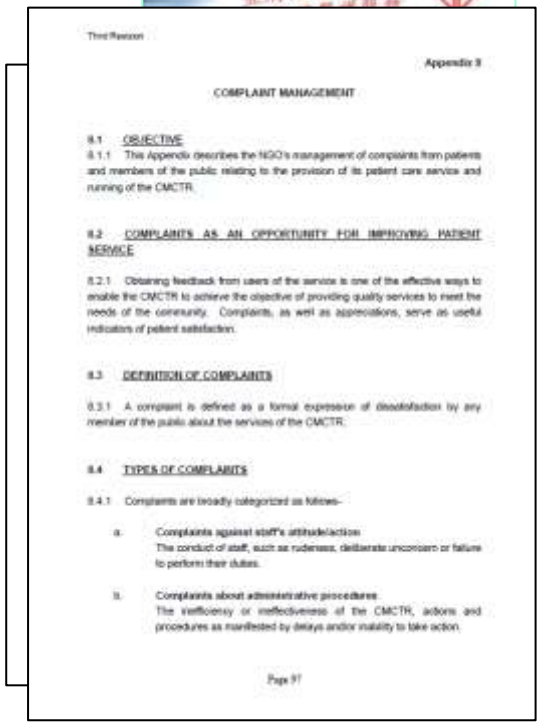
ENQUIRY & COMPLAINT

Emergency Contact of CMCTR/ CMP

- On-call numbers will be provided to pilot wards during ICWM pilot program
  - Clinical: Designated CMP, IM coordinator,
  - Administrative: Clinic Manager, CM Dept.

Complaint Management

- Complaint made to HA
  - follow existing complaint management system
- Complaint made to CM Service
  - Refer to CM Service provider (CMCTR) for further handling according to Manual on Governance of CMCTR
  - Inform CMD of the complaint cases



Third Revision

Appendix 9

COMPLAINT MANAGEMENT

9.1 OBJECTIVE

9.1.1 This Appendix describes the NGO's management of complaints from patients and members of the public relating to the provision of its patient care service and running of the CMCTR.

9.2 COMPLAINTS AS AN OPPORTUNITY FOR IMPROVING PATIENT SERVICE

9.2.1 Obtaining feedback from users of the service is one of the effective ways to enable the CMCTR to achieve the objective of providing quality services to meet the needs of the community. Complaints, as well as appreciations, serve as useful indicators of patient satisfaction.

9.3 DEFINITION OF COMPLAINTS

9.3.1 A complaint is defined as a formal expression of dissatisfaction by any member of the public about the services of the CMCTR.

9.4 TYPES OF COMPLAINTS

9.4.1 Complaints are broadly categorized as follows:-

a. Complaints against staff's attitude/action
The conduct of staff, such as rudeness, deliberate unconcern or failure to perform their duties.

b. Complaints about administrative procedures
The inefficiency or ineffectiveness of the CMCTR, actions and procedures as manifested by delays and/or inability to take action.

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INCIDENT REPORTING

Common Incidents of CM

- Acupuncture
  - Needle retain on patient body
  - Needle retain on patient bed/ linen
  - Needle stick injury (IOD) *remark: CMP injury =/= IOD
- Medication
  - Dispensing error - Wrong Patient

Flagging of ICWM cases

- HA Staff should reporting incidents in AIRS as usual.
- A checkbox of “ICWM” will be available in AIRS.
- The checkbox will show up only if wards in pilot program is selected.
- All incidents related to enrolled patients should be “ICWM” flagged, regardless of the nature and cause of the incidents.

Operational Manual

Pilot Project on Integrated Chinese-Western Medicine Programmes to be introduced to HA Patients

Operational Manual

Version	Effective Date
1	

Document Number	
Author	
Custodian	
Approved/ Endorsed By	
Approval Date	
Distribution List	

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Contents

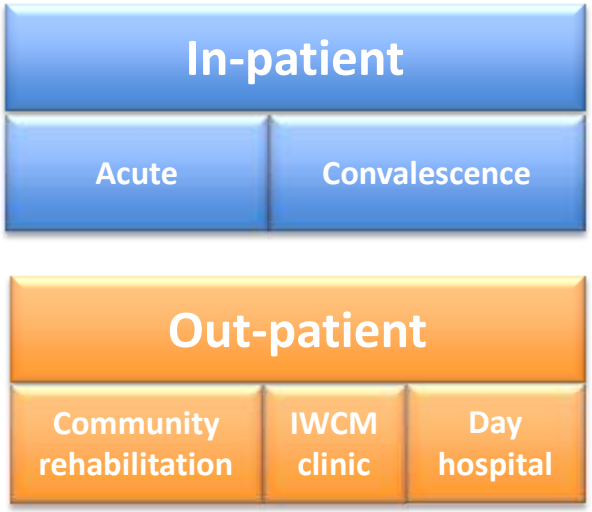
CLINICAL FRAMEWORK

Clinical Framework

Disease Selection

*Clear **inclusion and exclusion** criteria with specific WM and CM **treatment indication***

Service Scope



*Defined **entry & exit points** according to protocol*

Clinical management

*Assured **evidence-based and safe** practice*

Dual Framework

Operational Framework

- CM hospital service under HK laws

Clinical Framework

- 實證 = 實事求是
- **EBM** = Decisions based on best available information provided by **clinical research** (David Katz in Jekel's, 2014;p.93)

WM doctor's concerns - A Personal View

1. 中醫辨證論治 與 實證醫學 能積極互動嗎?
   - *IM-Stroke Clinical Protocol*

2. ?CM diagnosis – nature & reproducibility?
   - *Stroke CM diagnosis* (reproducible with clarity for communication & documentation)

3. ?CM treatment – would it affect WM treatment?
   - *Herbal toxicity and HDI* (safety)

4. *As a service feasibility pilot, efficacy is NOT a primary concern.*

IM-Stroke Pilot: Clinical Protocol (v2.1)

- **Objectives & Basic Requirements:**
  - To set up inpatient IM operation
  - To train relevant staffs
  - Safe and documentable IM practice

- **Inclusions:** Stable ischemic or hemorrhagic stroke of less than 1 mo. at designated medical wards under direct informed consent
- **Exclusions:** Unstable stroke; moderate-to-severe hemorrhagic stroke; thrombolytics within 24h; serious herbal adverse effects or herb-drug interactions

- **Clinical Approach:**

  WM Dx

  ➔ Different CM Zheng's

  ➔ CM treatments

  (whereas WM stroke mx & rehab continued unaffected)

- ***CM Diagnosis***
  1. *證型(syndrome)+/−or 症狀(symptom)+/−*
  2. *病位*
  3. *分期*

- 針灸治療:隨症狀
  - Flaccid / Spastic Paresis
  - Constipated / Incontinent / Cognition / Balance / Dysphagia / Dysphasia

  +/− 辨證候要素

- 中藥治療:辨證型
  - **肝陽暴亢，風火上擾證**（風+火）
  - **風痰瘀血，痹阻脈絡證**（風+痰+瘀）
  - **痰熱腑實，風痰上擾證**（風+火+痰+瘀+氣滯）
  - **氣虛血瘀**（氣虛+瘀）
  - **陰虛風動**（風+陰虛）

  +/− 辨證候要素

- **IM-Stroke and Q&S Outcomes**
  - Impairment & Disability: NIHSS, MMT, mBI, mFAC
  - Swallowing & Nutrition: Food & Fluid Consistency, RBHOMS, Albumin
  - Cognitive: MMSE
  - CM-related: CM-related adverse events, changing patterns of CM Syndromic conditions
  - Complications: Falls, restraint, bedsore, aspiration etc.
  - LOS, Deaths & Discharges, Caregiver, FU, Readmission

CM DIAGNOSIS & TREATMENT

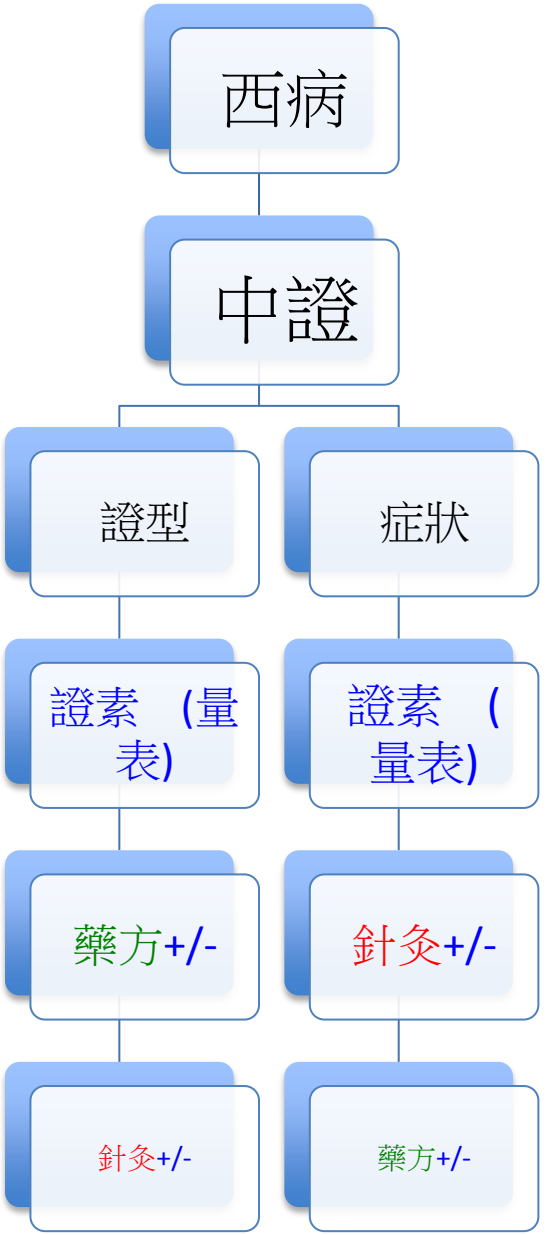
Clinical Approach of *CM Dx ➔ Rx* in IM-Stroke Pilot

CM Syndrome is made up of building blocks, called Syndrome Elements.

"+/-": 根據臨床的證素而加減

CM Diagnosis

1. *證型(syndrome) +/−*
   or
   症狀(symptom) +/−
2. *病位*
3. *分期*



方劑 與 証候要素(中風病性)

（参照：辛喜艳，张华，高颖. 缺血性中风病急性期常用中药复方与证候要素的关系. 中华中医药杂志,2010;25(8):1221－1225）

方剂	主治	風	火	痰	瘀	氣虛	陰虛	氣逆	氣滞	氣郁
天麻鉤藤飲	高血压頭痛眩晕失眠*1	✯	✯				√			
半夏白术天麻湯+/-	風痰上逆眩晕頭痛*2	✯		✯				√		
星蒌承氣湯+/-	痰熱腑實*3		✯	√					√	
溫胆湯+/-	氣郁痰阻少陽*4			✯						√
補陽還五湯	瘀阻脑络*5				√	✯				
鎮肝熄風湯	津亏高血压*6	✯	√				✯			

- **肝陽暴亢，風火上擾證**（風+火+陰虛）
- **風痰瘀血，痹阻脈絡證**（風+痰+氣逆+瘀）
- **痰熱腑實，風痰上擾證**（火+痰+氣滞+風+瘀）
- **氣虛血瘀**（氣虛+瘀）
- **陰虛風動**（風+陰虛+火）

註: 証候要素 (✯主, √次)

證素　(量表)

痰濕	分數
咳痰或喉中痰鳴	10
滑苔	9
膩苔	8
頭悶痛	6
脈滑	6
大便溏	4
舌胖大	3
厚苔	3
頭重	3
舌有齒痕	2
神情呆滯	2
渴不欲飲	2
納呆	2
口黏膩	2
表情淡漠或寡言少語	1
體型肥胖	1
頭昏或頭暈	1

ISCMSDS-2008

結或代			1		1	
澀			8			
沉					4	
弱					4	
緩					5	
	內風	內火	血瘀	痰濕	氣虛	陰虛
MAX scores	100	68	73	65	81	85
總分						

Circle corresponding score - a diagnostic feature identified; "X" : Unable to assess.

Diagnosis established for a CM diagnostic element if summation score of that particular element = or > 10

Diagnosis established when summation score of that particular element = or > 10

根據證型選擇處方

參照：辛喜艳，张华，高颖. 缺血性中风病急性期常用中药复方与证候要素的关系. 中华中医药杂志,2010;25(8):1221－1225）

- **中經絡: 肝陽暴亢，風火上擾證**（風+火）
  - 法：平肝潛陽，清肝熄風
  - 方：**天麻鉤藤飲**《雜病證治新義》
  - 藥：天麻、鉤藤、梔子、黃芩、牛膝、茯神、生石決明、杜仲、益母草、桑寄生、夜交藤
- **中經絡: 風痰瘀血，痹阻脈絡證**（風+痰+瘀）
  - 法：平肝熄風，化痰祛瘀
  - 方：**半夏白術天麻湯**加味《醫學心悟》
  - 藥：半夏、白術、天麻、陳皮、茯苓、生薑、大棗 + 血瘀證用藥(參照4.2.3.)
- **中經絡: 痰熱腑實，風痰上擾證**（風+火+痰+瘀+氣滯）
  - 法：清熱化痰，通腑熄風，行氣化瘀
  - 方：**星蔞承氣湯**加味《臨床中醫內科學》/ **溫膽湯**加味《三陰極一病證方論》
  - 藥：膽南星、全瓜蔞、生大黃、芒硝 / 半夏、陳皮、甘草、枳實、竹茹、生薑、茯苓、大棗 + 血瘀證用藥(參照4.2.3.)
- **中經絡: 氣虛血瘀**（氣虛+瘀）
  - 法：益氣活血，化瘀通絡
  - 方：**補陽還五湯**《醫林改錯》
  - 藥：黃芪、當歸尾、川芎、桃仁、地龍、赤芍、紅花
- **中經絡: 陰虛風動**（風+陰虛）
  - 法：鎮肝熄風，滋陰潛陽
  - 方：**鎮肝熄風湯**《醫學衷中參西錄》
  - 藥：懷牛膝、生龍骨、生牡蠣、生白芍、天冬、生麥芽、玄參、川楝子、茵陳蒿、生龜板、代赭石

根據證候要素加減中藥

(證候要素參照: 張聰。從病機看中風病證候要素。中華中醫藥學刊2007；3期)

主要證候要素

- ***風：***加天麻、鉤藤、地龍、僵蠶、全蠍、水牛角。
- ***火熱：***加夏枯草、丹皮、珍珠母、梔子、黃芩、知母、玄參、生地。
- ***痰：***加法半夏、旋複花、膽南星、天竺黃、川貝母、竹茹、瓜蔞。
- ***血瘀：***加丹參、桃仁、紅花、赤芍、三七、川芎、牛膝、郁金、雞血藤、毛冬青。
- ***氣虛：***加黃芪、黨參、太子參、白朮、山藥。
- ***陰虛：***加白芍、天冬、麥冬、石斛、百合、黃精、女貞子、旱蓮草、龜板、鱉甲。

次要證候要素

- ***陽亢：***加代赭石、珍珠母、白芍、龍骨、牡蠣。
- ***氣鬱：***加柴胡、白芍、郁金、合歡皮/花、柏子仁、石菖蒲、遠志、夜交藤。
- ***氣滯：***加枳實、厚樸、陳皮、烏藥、佛手、木香。
- ***氣逆：***加柿蒂、丁香（畏郁金）、旋複花。
- ***水濕：***加茯苓、澤瀉、白術、薏苡仁、砂仁。
- ***陽虛：***加杜仲、巴戟、淫羊藿、肉蓯蓉、補骨脂、核桃仁。

中風病辨證論治與實證醫學

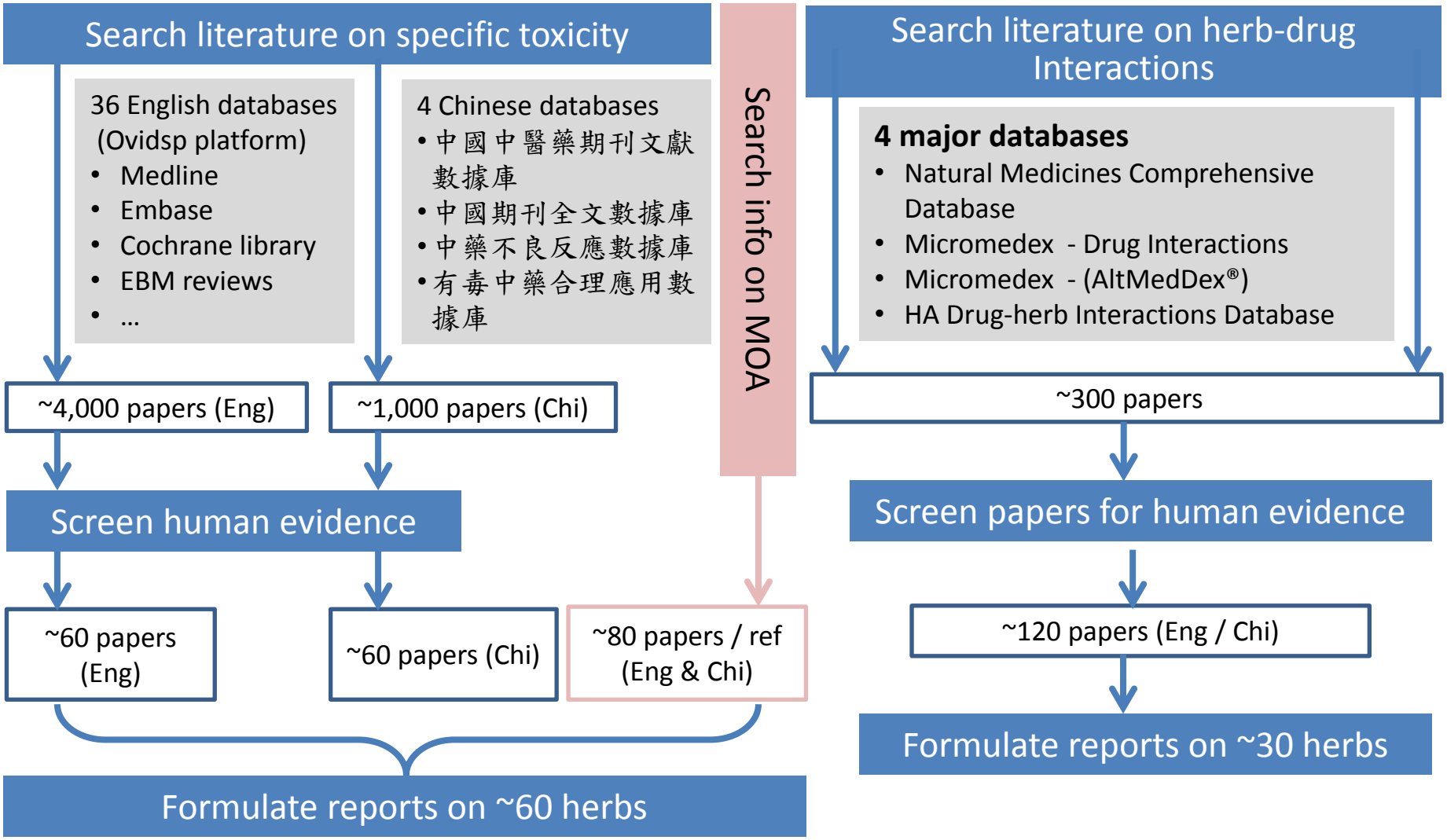
- ***證型***參照：1983年中國中醫藥學會內科學會組織中醫臨床專家討論擬定《中風病中醫診斷療效評定標準》“一代標準”；
- ***證候要素***參照：2008年國家科技部“973”計畫“缺血性中風病證結合的診斷標準與療效評價體系研究”課題組研製出《缺血性中風證候要素診斷量表》；
- ***處方***參照：辛喜豔，張華，高穎. 缺血性中風病急性期常用中藥複方與證候要素的關係. 中華中醫藥雜誌(原中國醫藥學報),2010;25(8):1221—1225。

HERBAL TOXICITY & HERB-DRUG INTERACTION

中藥治療中風注意事項(“or”)

- Patients with severe dysfunction of liver or kidney should be excluded from herbal intervention.
- Chinese herbal treatment with known serious adverse interaction (e.g. major bleed) with anti-platelets (e.g. aspirin, clopidogrel, persantin, cilostazol), anti-coagulants or other concurrent western medicines should be avoided.

Search Methodology



Risk-stratification Methodology

- Level of evidence
- Quality (validity, applicability, size etc of studies) of the information
- Severity of reaction
- Expert opinion

I	a - Meta-analysis of RCT b - At least one RCT
II	a - At least one well designed non-R CT b – At least one well designed experimental trial
III	Case, correlation, and comparative studies.
IV	Opinion from panel of experts

Risk Stratification Matrix – Herb X

Level of Evidence / Quality of studies	I	II	III	IV
Good	1	2	2	2
Fair	2	2	3	3
Poor	2	3	3	3
Recommendation				
Other remark				

1 = high risk
2 = moderate risk
3 = low risk
4 = No reported risk

Staff Engagement & Training

Induction & Regular Activities:

- To CM staffs on WM & CM
- To WM staffs on CM

Clinical Audit, Interim Review, Final Independent Evaluation

- Prepare for the first Chinese Medicine Hospital in Hong Kong

THANK YOU

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