Development and Implementation of Korean Medicine Clinical Practice Guideline

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I. DEFINITION OF CPG
II. BACKGROUND AND STRATEGIES
III. CPG-KM DISSEMINATION
IV. DISCUSSION
The Institute of Medicine defines clinical practice guidelines (CPGs) as "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."


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**Background and pre-process**

- **Various diagnosis and treatment**
- **No standardised KM medical practice**

**Analysis of domestic and foreign trends**
- Korea: 16 (based on expert opinion)
- China: 31 (based on EBM)
- Japan: 17 (based on EBM)

**Selection of high priority 12 diseases**
- 50 diseases selected by WHO as top priorities, survey results of experts, data provided by Statistics Korea, disease categories for CPG development by the China Academy of Chinese Medicine Science
  - 2013: Facial palsy, HIVD, Atopic dermatitis
  - 2014: Shoulder pain, Ankle sprain
  - 2015: Obesity, Depression
  - ETC: Dizziness, Headache, Insomnia, Rhinitis, Menopausal disorder

**Perceptions survey on CPG-KM in Korea**
- "97.5% of experts thought that the development of CPGs was necessary..."
  - Three categories (perceptions on CPGs, priority diseases and symptoms for CPG development, demographic characteristics of respondents) - Responder 1,226 (8.5% of 14,485)

**Establishment of a network of domestic and foreign experts**
- Establishment of CPG network
- Hold International symposium
- European Journal of Integrative medicine CPG Special issue publishing
Evidence Based Medicine

Priority diseases in Korea
- Facial palsy
- Atopic dermatitis
- HIV
- Ankle sprain
- Shoulder pain
- Obesity
- Depression
- Depression

Evidence and Recommendation

Evidence Based Clinical Practice Guideline

Improvement of health quality
Standardization of health treatment
Evidence production through clinical trial

CPG-KM Project strategy

Practical experience and expertises in the clinical field

Systematic review

Evidence Based Medicine

Evidence production through clinical trial

Building construction projects of CPG-KM

Guideline Executive Committee
- Research Unit
- Support for CPG development
- Education for developers
- Selection and Dissemination
- Implementation
- Assessment

Research Hub

Guideline Development Group

Advisory committee

Monitoring committee

Research Unit

Feedback

Feedback
Increasing consistency and credibility for CPG reporting of KM
- Reflecting the particularity of KM (KM pathology/PI)
- Reflecting EBM method—Evidence level and recommendation

**Process of developing PRIDE-CPG-KM**

**Revising grading of Recommendations Assessment, Development, and Evaluation**

- Following GRADE methods, modified it considering particularity of KM
  - To clarify the decision for evidence level, develop overall body, evidence flow chart
  - RG considering benefit, values and preference and supporting resource

<table>
<thead>
<tr>
<th>Grade</th>
<th>4 levels</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>We are very confident that the true effects lies close to that of the estimate of the effect.</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.</td>
<td></td>
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<tr>
<td>Low</td>
<td>Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.</td>
<td></td>
</tr>
<tr>
<td>Insufficient</td>
<td>We have very little evidence in the effect estimate: The true effect is likely to be substantially different from the estimate of the effect.</td>
<td></td>
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<thead>
<tr>
<th>Grade</th>
<th>5 grades</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>Recommended when the level of evidence is &quot;high&quot;, there is a clear benefit and the level of use in clinical settings is high.</td>
<td></td>
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<tr>
<td>B</td>
<td>Assigned when the level of evidence is &quot;moderate&quot;, the benefits are reliable, and the level of use in clinical settings is high or moderate. Although relevant studies providing evidence supporting the recommendation may be lacking, the clinical benefit is clear.</td>
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<tr>
<td>C</td>
<td>Assigned when the level of evidence is &quot;low&quot;, the benefits are not reliable, but the recommendation's level of use in clinical settings is high or moderate.</td>
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<tr>
<td>D</td>
<td>Assigned when the level of evidence is &quot;low&quot; or &quot;insufficient&quot;, the benefits are unreliable, harmful results may arise, and the recommendation's level of use in clinical settings is low.</td>
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<tr>
<td>GPE</td>
<td>Due to the lack of evidence-based medical information, the level of evidence is &quot;low&quot; or &quot;insufficient&quot; and the benefits cannot be evaluated. This rating is assigned based on the CPGs development group's experience and a high level of use in clinical settings.</td>
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**Process of making criteria**

- Consisting Experts group (KIOM, KMU, NECA (total 13 expert))
- Provisional EL, GR
- Meeting of Experts group with KM-CPGs
- Consultation from Experts (Total 3 times)

**Grading criteria**

- GRADE
- SIGN
- GRADE-AHRQ
- CM-CPGs
Development process and expert consensus

- Establishment of a network of clinical experts to develop clinical practice guideline
- Making key question
- Literature Search and Quality Assessment
- Data Selection and extraction
- Drawing evidence and recommendation using GRADE system
- Classification of CPG statement and Peer review
- Making consensus for recommendations using Delphi process
- Internal and External Scrutiny and Approval

Compiled a final recommendation on the draft using the Delphi technique.

Using survey monkey
- Conducting the questionnaire on the draft of the recommendation
- Review Committee from various clinic consultation users as well as users and methodologists

Education program package for evidence based clinical practice guideline

- Adaptation of education program
- Clinical care provider
- Students in Oriental university
- CPG development groups
- Individualized educational program
- Feedback using questionnaire

Feedback
Dissemination and Implementation of CPG in Korea
Promote understanding of EBM
Improving research practice
Development of Evidence based CPG

DEVELOPMENT
• Selection of frequency disease
• Multidisciplinary Developing group
• Drawing key clinical question using PICO considering clinical situation
• Grading Evidence and recommendation using GRADE approach Expert consensus using Delphi method

PEER REVIEW/APPROVAL
Expert consensus

PUBLISH
2014 shoulder pain
2015 ankle sprain
2015 facial palsy
2015 herniated intervertebral disc
2015 atopy/dermatitis
2015 depression
2015 obesity

Acupuncture recommendations in 2014 CPG

Shoulder pain
20 recommendations to acupuncture (acupuncture (11), pharmacopuncture (2), Warm needle(2), Fire needle(1), Needle-Knife(1), and Electro acupuncture (3))

“A manual acupuncture treatment is recommended to alleviate the pain and improve the range of motion and shoulder joint functions of an adult shoulder pain patient. (A/Moderate)”

“A combination of a manual acupuncture treatment and self-exercise must be considered to enhance improvement in shoulder pain and shoulder joint functions. (B/Moderate)”

Ankle sprain
6 acupuncture recommendation statements (acupuncture (n=4), pharmacopuncture (n=2), and Electro acupuncture (n=1))

“Acupuncture treatment is recommended to mitigate acute ankle sprain symptoms in adults. (A / Moderate)”

“Acupuncture should be considered instead of conventional nonsurgical treatment for acute ankle sprain in adults. (B/Moderate)”
Acupuncture recommendations in 2015 CPG

**Facial palsy**

6 recommendations to manual acupuncture

"It is recommended that acupuncture treatment be initiated for facial palsy patients in the acute and stationary phases (within 1–3 weeks) (Recommendation B, Evidence Ib)

**HIVD (Herniated intervertebral disc)**

6 recommendation statements (acupuncture (n = 3), pharmacopuncture (n = 3))

"Acupuncture treatment is recommended as an effective intervention for Lumbar HIVD patients to relieve pain improve their bodily function." (Recommendation A, Evidence Ib)

**Atopy dermatitis**

6 recommendation statements (acupuncture (n = 2), Herbal medicine (n = 4))

"Manual acupuncture is recommended to relieve pruritus in AD (Recommendation A, Evidence Moderate)

For manual acupuncture, BL20, BL21, DU4, LI4, LI11, ST36, BL40, and ST40 should be considered as the major acupuncture points. In case of auricular acupuncture, CO13, CO4, CO18, and FT4 should be considered. (Recommendation GPP, Evidence Insufficient)

Acupuncture recommendations in 2016 CPG

**Depression**

11 recommendations to acupuncture (acupuncture (7), Electro acupuncture (4))

"Acupuncture combination of usual care should be considered preferentially to treat BDI-II score ≥20 points of moderate depression than usual care. (B/Moderate)"

"Electro acupuncture should be considered to treat post-stroke depression. (B/Moderate)"

**Obesity**

5 recommendations to acupuncture (acupuncture (3), Electro acupuncture (1), and pharmacopuncture (1))

"For the treatment of obese patients, the treatment of manual acupuncture should be considered more than ear acupuncture to show the significant effects on BW loss. (B/Moderate)"
Clinical Decision Support System (DSS)

Obesity

Shoulder pain

Evaluation of the clinical application of a leaflet for clinical practice guidelines

Case report form, standard operation procedure and research protocol development

Explanation of the overall treatment and diagnosis based on a leaflet that includes recommendations

The first evaluation trial with KM CPGs

Same treatments except leaflet between two groups

<table>
<thead>
<tr>
<th>CRIS</th>
<th>[protocol registration](CRIS No: KCT0001761)</th>
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<tr>
<td>CRIS</td>
<td>[protocol registration](CRIS No: KCT0001762)</td>
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CPG leaflets for dissemination

- Randomized controlled trial with shoulder pain, HIVD for Evaluation of the clinical application of a leaflet for clinical practice guidelines
- Case report form, standard operation procedure and research protocol development
- Explanation of the overall treatment and diagnosis based on a leaflet that includes recommendations

The first evaluation trial with KM CPGs
Evaluation of the clinical application of a leaflet for CPG of shoulder pain

From June 1 to November 30, 2015,
Wonkang Korean medicine hospital

Cross over design with randomly assigned to one of two groups (the leaflet group or the standard care group) at the first visit

Group 1 – used a leaflet for the first session of the assessment of the degree of satisfaction, but did not for the second one

Group 2 – Conversely, did not use a leaflet for the first session of the assessment and did for the second one.

In group 1, the mean degree of patient satisfaction was 23.32 points in the leaflet group and 23.36 in the non-leaflet group. These results indicate that there was a slight increase in patient satisfaction.

Results

Evaluation of the clinical application of a leaflet for CPG of HIVD

From November 1 to November 30, 2015,
Jaseng Korean medicine hospital

Randomly assigned to one of two groups (the leaflet group or the standard care group) at the first visit

The patients’ satisfaction levels: intervention group – 88%, control group – 64%.

The levels of patient satisfaction of understanding with the doctors’ explanation: intervention group – 92%, control group – 64%.

Satisfaction of the doctors: 100% in leaflet users
Ease of persuasion for treatment (84%)
– limitations: time consuming (48%),
Explanation of TKM terms (90%)
Prospective and retrospective studies for safety of pharmacopuncture

- Reflected in the safety section of the revised CPG Recommendation in 2015
- No major adverse events were found, and all were either transient or mild adverse events
- Reporting Guide for adverse event is needed

### HIVD
- A single site (semyung univ)
- 51 patients from prospective observational study
- Adverse events: 10 patients (19.6%)
  - pain(injection) 3 cases, pain(after injection) 4 cases, pain (after 30 minutes from injection) 1 case, subcutaneous bleeding 2 cases

### Facial palsy
- Three sites (dongshin, woosuk, sangji univ)
- 1035 patients from retrospective chart review
  - Adverse events: 12 patients (1.2%)
  - itching sign 4 cases, edema 3 cases, nodule 1 case, facial edema 1 case, pain 2 cases, subcutaneous bleeding 1 cases

Comparison between KM-CPG and CM-CPGs

### Recommendation

<table>
<thead>
<tr>
<th>KM-CPG</th>
<th>CM-CPG</th>
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</table>
| Facial palsy | - Consist of diagnostic and treatment
  - All KM intervention (acupuncture, EA, herbal medicine, moxibustion, pharmacopuncture, cupping, physical therapy) |
  - Three sites (dongshin, woosuk, sangji univ)
  - 1035 patients from retrospective chart review
  - Adverse events: 12 patients (1.2%)
  - itching sign 4 cases, edema 3 cases, nodule 1 case, facial edema 1 case, pain 2 cases, subcutaneous bleeding 1 cases |

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<th>KM-CPG</th>
<th>CM-CPG</th>
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</table>
| Atopy | - Consist of severity, patients types
  - Treatments based on PI (acupuncture only) |
  - All KM intervention (acupuncture, herbal medicine, moxibustion, pharmacopuncture, cupping, relaxation methods) |
  - Diagnosis, treatment, prevention
  - Treatment based on PI (Herbal medicine-internal and external, acupuncture, dietary regulation, life style) |

### Quality of CPGs (AGREE II)

<table>
<thead>
<tr>
<th>Items</th>
<th>Previous KM-CPG</th>
<th>CM-CPG</th>
<th>KIOM KM-CPG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope and purpose</td>
<td>60%</td>
<td>79.96%</td>
<td>81.48%</td>
</tr>
<tr>
<td>Stakeholder involvement</td>
<td>56.11%</td>
<td>61.28%</td>
<td>75.56%</td>
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<tr>
<td>Rigor of development</td>
<td>42.7%</td>
<td>80.95%</td>
<td>70.00%</td>
</tr>
<tr>
<td>Clarity and presentation</td>
<td>62.50%</td>
<td>70.88%</td>
<td>78.52%</td>
</tr>
<tr>
<td>Applicability</td>
<td>20.31%</td>
<td>27.09%</td>
<td>29.17%</td>
</tr>
<tr>
<td>Editorial independence</td>
<td>44.58%</td>
<td>84.16%</td>
<td>92.78%</td>
</tr>
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Solution for improving KM-CPGS by analyzing previous KM-CPGS

- Reflecting on development of EBM KM-CPGS
- Superiority in all of items
ISEB-CPG-TM

The 1st (2012.09.17.)
- Current situation of CPGs development in TM
  6 speakers from 4 countries

The 2nd (2013.10.22.)
- Methodological issue in CPGs of TM
  7 speakers from 4 countries
  - Special issue about CPGs

The 3rd (2014.10.21.)
- [Implementation of EBM CPGs]
  6 speakers from 7 countries
  - Discussion about EB-CPG-TM Network

The 4th (2015.10.27.)
- Challenge and Solution of CPGs development of TM in the future
  10 speakers from 6 countries

ISEB-CPG-TM

Current situation of CPGs development in TM
- Adaptation of clinical doctor’s opinion
- Recommendation of clinical expert for CPG development
- Formal approval from Society
- Research collaboration with General practitioner
- Standard form of development and dissemination for Evidence Based CPG

Standardization of health treatment
Improvement of health quality
Evidence production through Clinical trial

CPG development
• Report evidence via well-designed, randomized, controlled trials on therapeutic techniques frequently used clinically
• Reproducibility and reliability of CPG methodology considering particularity of KM

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