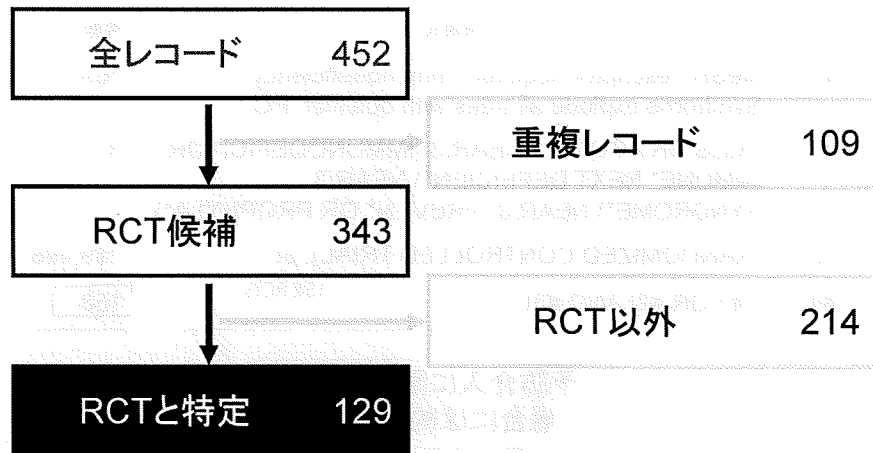
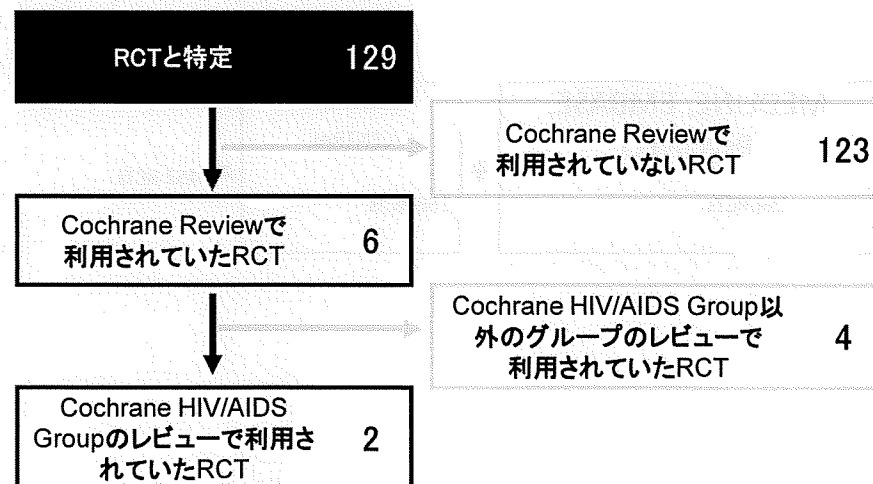


## 2-1. RCT検索結果から RCTを特定



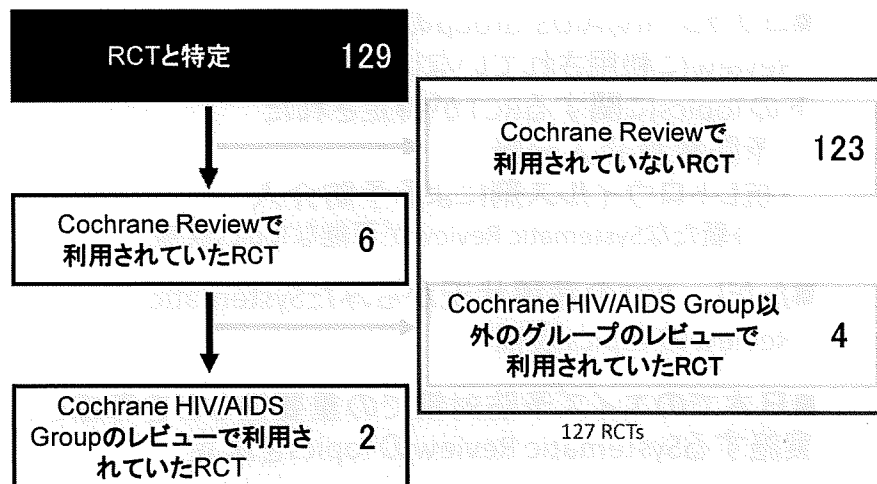
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## 2-2. Cochrane HIV/AIDS Groupのレビューで 利用されていないRCTの特定



16

## 2-2. Cochrane HIV/AIDS Groupのレビューで 利用されていないRCTの特定



17

## 2-3. Cochrane HIV/AIDS Groupのレビューで 利用されていないRCTのTopicsによる分類

Category 1	Category 2	RCT数
Behavioral, Social and Policy Prevention	•Education	83
	•Skills training	
	•Community-based intervention	7
	•Health Service Program •Media campain	
Biomedical Prevention	•Antiretroviral agents	8
	•Vaccines	4
	•Others	8
Therapeutics, Prognostics and Diagnostics	•Antiretroviral agents	10
	•Others	7
計		127

18

### 3. 新たに実施するSystematic Review Topics候補の抽出

- コクラン HIV/AIDS GroupのSystematic Reviewに利用されていないRCTを分類し、主に以下のTopicsに関するRCTが特定された
  - ・予防教育介入分野
  - ・抗レトロウイルス剤による予防介入  
→新たなSystematic Reviewが可能なTopics候補
- ただし、RCTの蓄積状況からみたSystematic ReviewのTopics候補
- 日本でのエイズ予防対策での重要性などを考慮し、実施するSystematic ReviewのTopicsを決定

19

## 方法

質の高い研究で検討されたHIV予防法を系統的検索

日本で導入可能性のあるものについて系統的レビュー

系統的レビューの結果に基づき決断分析

フォーマルコンセンサス法を用いてベストの方法を策定

## 日本の診療ガイドラインのための ガイドライン

- I. システマティックレビュー/メタアナリシス
  - II. 1つ以上のランダム化比較試験による
  - III. 非ランダム化比較試験による
  - IV. 分析疫学的研究(コホート研究や症例対照研究による)
  - V. 記述研究(症例報告やケース・シリーズ)による
  - VI. 患者データに基づかない、専門委員会や専門家個人の意見
- なお、複数のタイプがある場合は、エビデンスのタイプの質の高いタイプをとる。ただし、白人Caucasian研究にもとづくタイプと日本人研究にもとづくタイプが異なる場合などは、それぞれ別記する。

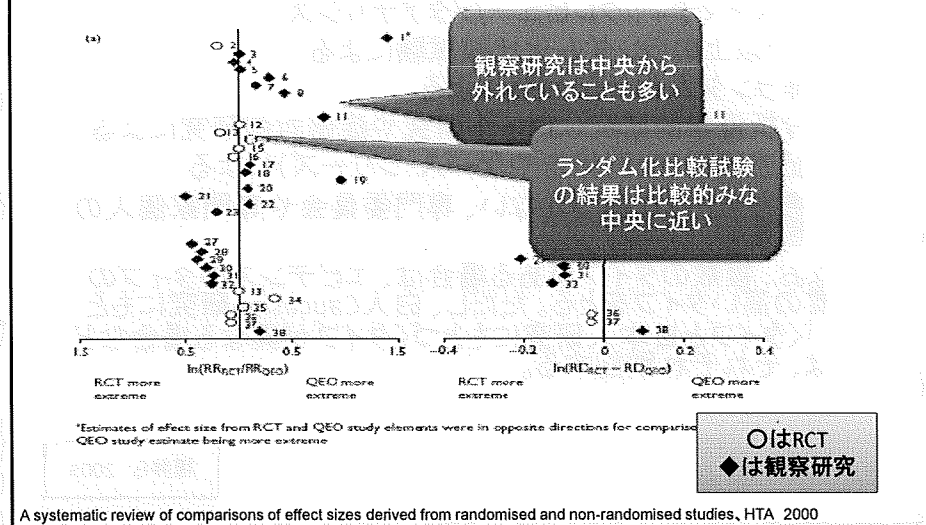
福井ら 2003

## 日本の診療ガイドラインのための ガイドライン

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福井ら 2003

## 観察研究とランダム化比較試験



## 改めて、検索で見つかった研究を整理

感染ルート	予防方法	RCTの数	検討アウトカム
性行為	教育	113	性行動の変化
	若者向け教育	56	
	マスメディア	18	
	VCT	10	
	他の性感染症治療	8	
	ワクチン	4	感染減少
母子感染	ARV	23	感染減少
血液接触	医薬品	19	感染減少
	その他	4	

## 母子感染予防

対象	介入	比較	アウトカム
妊娠女性	-Zidovudine 500, 800, 1500 mg -Ribavirin 600, 800, 1000 mg -Nevirapine 200 mg -Aerosol Pentamidine -Filgastrim	プラセボ	感染 死亡率 AIDS発症など

23件のランダム化比較試験

## VCT

HIV感染は検討  
されていない！

対象	介入	アウトカム
ドラッグ使用者 性行為感染症感染者 貧困女性 大学生 若者	HIV予防カウンセリング HIV教育 仲間による教育 文化的介入 +HIV検査	性行動の変化 コンドーム使用 HIV検査

10件のランダム化比較試験

## 他に日本で質の高い科学的根拠で検討されている予防介入はありますか？

性行為	教育	113	性行動の変化
	若者向け教育	56	
	マスメディア	18	
	VCT	10	
	他の性感染症治療	8	感染減少
	ワクチン	4	
母子感染	ARV	23	感染減少
血液接触	医薬品	19	感染減少
	その他	4	

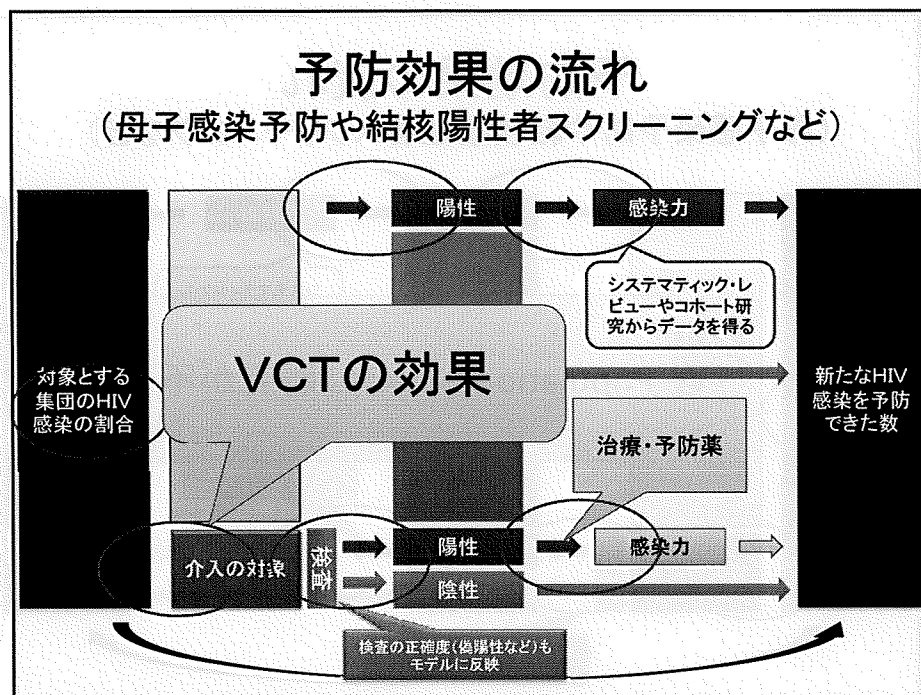
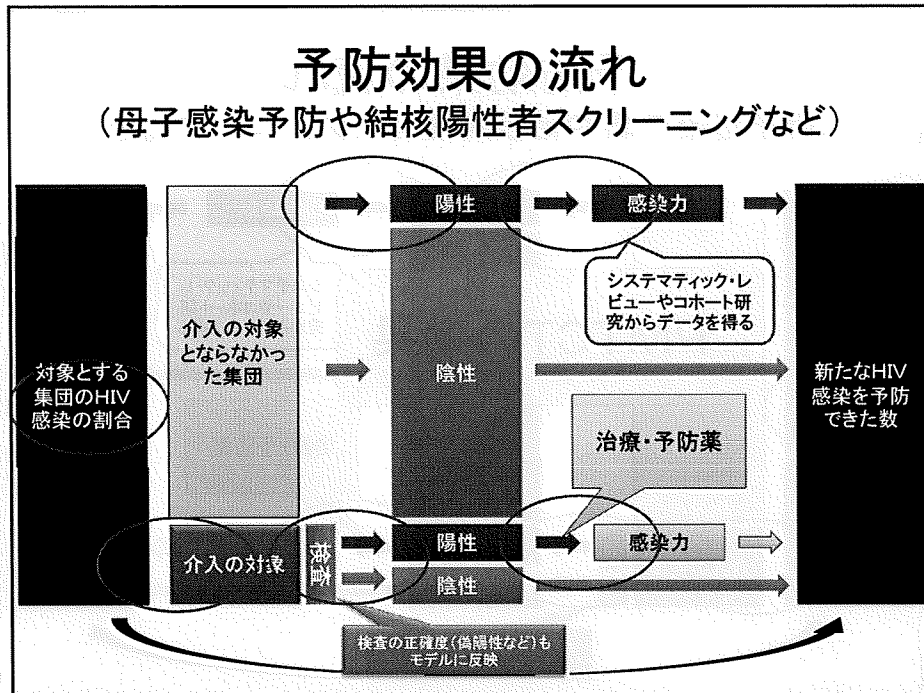
## 方法

質の高い研究で検討されたHIV予防法を系統的検索

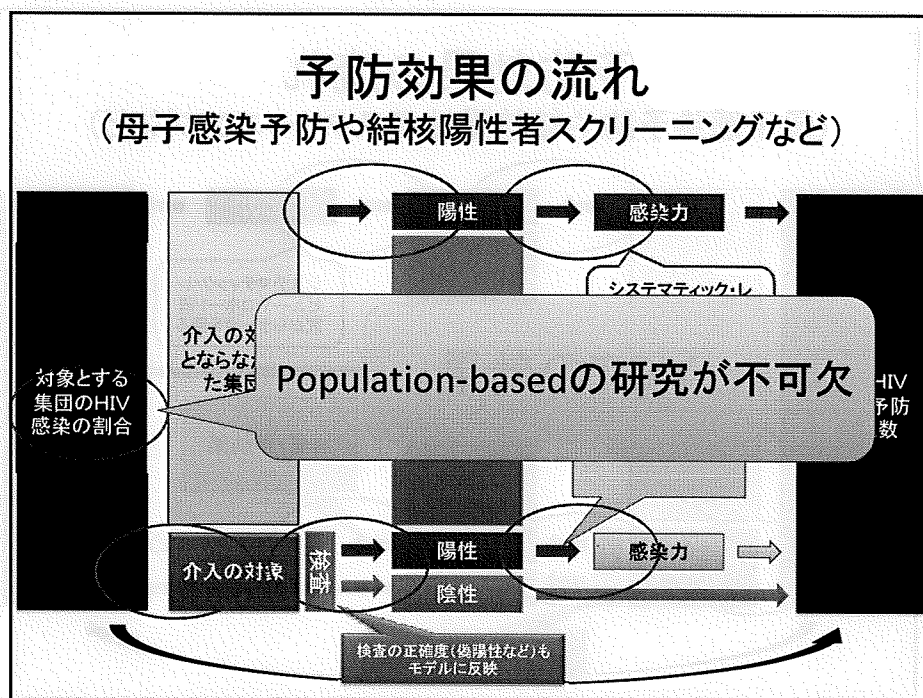
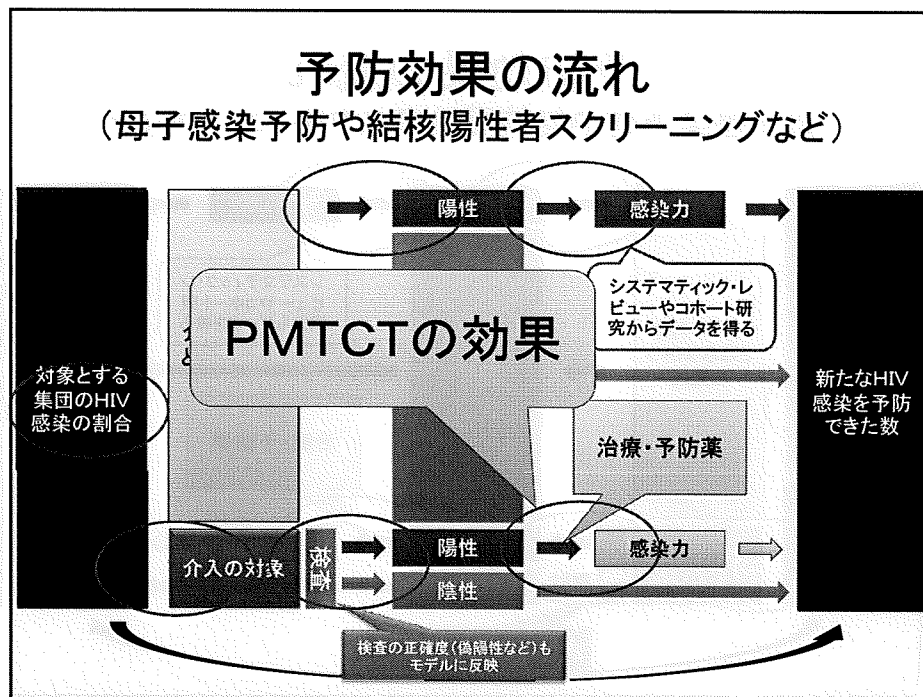
日本で導入可能性のあるものについて系統的レビュー

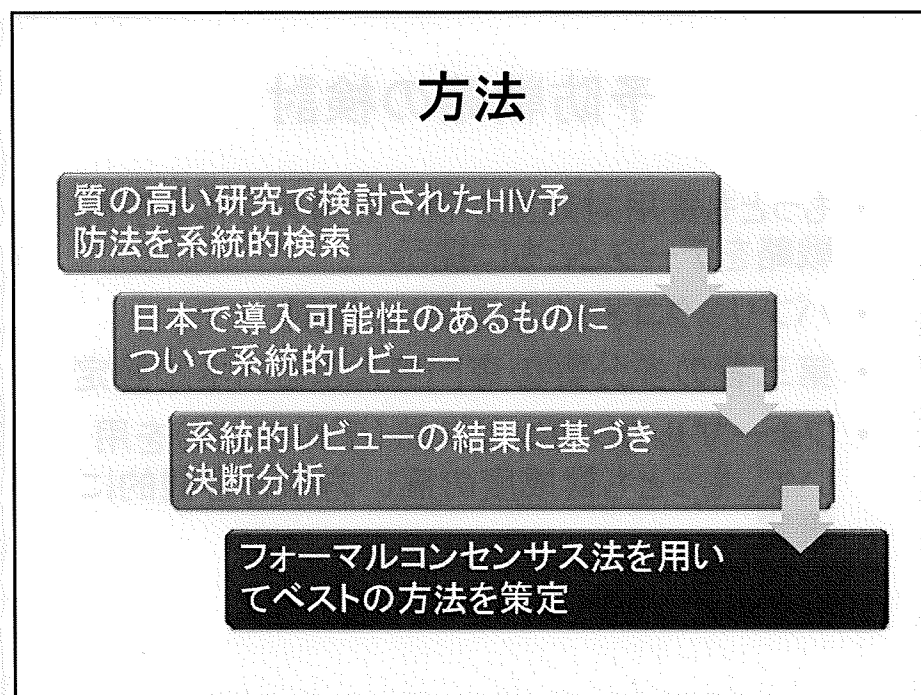
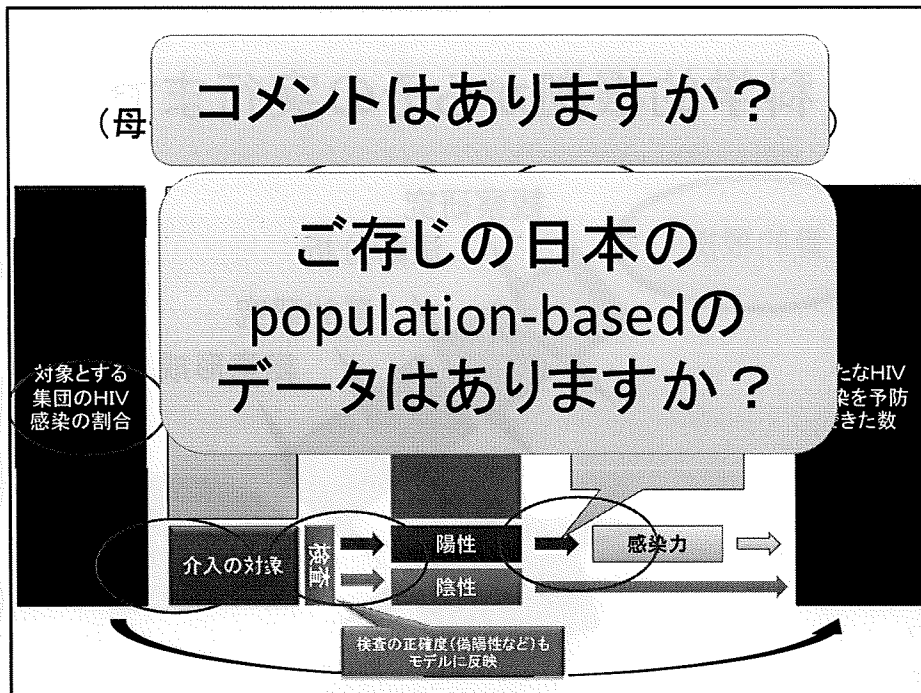
系統的レビューの結果に基づき決断分析

フォーマルコンセンサス法を用いてベストの方法を策定

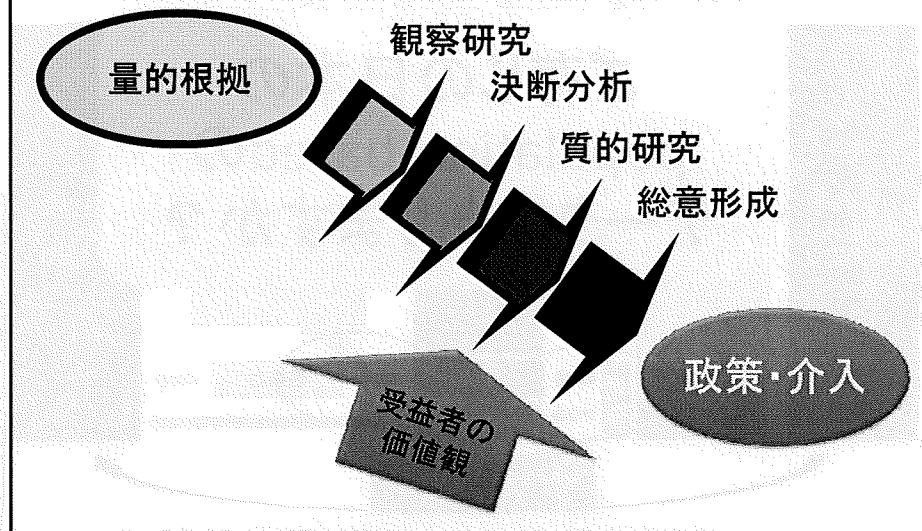








## 科学的根拠からその実行まで



## 予防戦略の検討

- もっとも費用対効果が高いと考えられる予防戦略をデータとともに提示
- パブリックコメントを募集し、検討
- 第三者の多分野の専門家によるパネル設定
- フォーマルコンセンサス法(デルフィ法)を用いて、もっとも賛成度の高い方法を客観的に策定

## 考え方

- HIVの予防は高い優先事項
- 血税をつぎ込むのであったら説明責任に耐える科学的根拠が必要
- 政策策定に受益者や一般市民の価値観を正しく反映する必要

## 添付資料 5

HIV/AIDS Group topic list

## HIV/AIDS Group topics list (Cochrane Library 2009:2)

- R = finished review
- P = protocol for review (in progress)
- "Registered Titles" are listed, not yet classified, at the bottom of this page.

### Reviews of Behavioral, Social and Policy Prevention

#### ★ Sex-related HIV risk reduction

- R Behavioral interventions to reduce risk for sexual transmission of HIV among men who have sex with men

#### ★ Condom use

- P Structural and community-level interventions for increasing condom use to prevent HIV and other sexually transmitted infections.
- P Behavioral interventions for increasing condom use in women with HIV

#### ★ Drug-related HIV risk reduction

- Drug-related behavior change
  - P Psychosocial interventions for the reduction of injection and sexual risk behaviour for preventing HIV in drug users

#### ★ Interventions targeting specific populations

- P Behavioral interventions for decreasing HIV infection in racial and ethnic minorities in high-income economies
- P Behavioral interventions for reducing HIV infection in employees in occupational settings
- P Behavioral interventions to reduce the transmission of HIV infection among commercial sex workers and their clients in developed countries
- P Behavioral interventions to reduce the transmission of HIV infection among commercial sex workers and their clients in developing countries
- P Harm reduction interventions to prevent HIV/AIDS transmission in involuntary detainees

- **R** Interventions for improving the psychosocial wellbeing of children affected by HIV/AIDS.
- **P** Interventions to modify sexual risk behaviours for preventing HIV in homeless youth
- **P** Peer-based interventions for reducing morbidity and mortality in HIV-infected women

★ **Specific types of interventions**

- **R** Abstinence-only programs for HIV infection prevention in high-income countries
- **R** Abstinence-plus programs for HIV infection prevention in high-income countries
- **R** Home-based HIV voluntary counseling and testing in developing countries
- **P** Interventions for reduction of stigma in people with HIV/AIDS
- **R** Mass media interventions for promoting HIV testing
- **P** Rapid HIV tests and counseling for pregnant women for preventing mother-to-child HIV transmission
- **P** Routine vs. voluntary HIV testing for increasing HIV testing rates
- **P** School-based interventions to postpone sexual intercourse and promote condom use among adolescents

**Reviews of Biomedical Prevention**

★ **Post-exposure prophylaxis**

- **R** Antiretroviral post-exposure prophylaxis (PEP) for occupational HIV exposure
- **P** Effectiveness and safety of HIV post-exposure prophylaxis after sexual, injecting-drug-use or other non-occupational exposure.

★ **Pre-exposure prophylaxis**

- **R** Antiretroviral pre-exposure prophylaxis (PrEP) for preventing HIV in high-risk individuals

★ **Prevention of perinatal transmission**

- **R** Antiretrovirals for reducing the risk of mother-to-child transmission of HIV infection

- R Efficacy and safety of cesarean delivery for prevention of mother-to-child transmission of HIV-1
- R Interventions for preventing late postnatal mother-to-child transmission of HIV
- R Interventions for reducing the risk of mother-to-child transmission of HIV infection
- R Vaginal disinfection for preventing mother-to-child transmission of HIV infection
- R Vitamin A supplementation for reducing the risk of mother-to-child transmission of HIV infection

★ **Condom efficacy**

- R Condom effectiveness in reducing heterosexual HIV transmission
- P Female condom for preventing HIV and sexually transmitted infections

★ **STI treatment**

- R Population-based interventions for reducing sexually transmitted infections, including HIV infection

★ **Microbicides**

- R Nonoxynol-9 for preventing vaginal acquisition of HIV infection by women from men

★ **Circumcision**

- R Male circumcision for prevention of heterosexual acquisition of HIV in men
- P Male circumcision for prevention of homosexual acquisition of HIV in men

★ **Vaccines**

★ **Safety of blood products**

★ **Syringe and needle use**

**Reviews of Therapeutics, Prognostics and Diagnostics**

★ **Antiretrovirals, including protease inhibitors**

→ Combination therapy

- P A combination drug of abacavir-lamivudine-zidovudine (Trizivir®) for treating HIV infection and AIDS



- **R** Antiretroviral regimens for patients with HIV who fail first-line antiretroviral therapy
- **P** Efavirenz versus nevirapine as a non-nucleoside reverse transcriptase inhibitor in initial combination antiretroviral therapy for HIV infection
- **P** Effectiveness and safety of first-line fixed-dose TNF + EMC + EFZ for patients with HIV
- **P** Ritonavir-boosted protease inhibitor-containing regimens versus non-boosted protease-inhibitor-containing regimens for reducing morbidity and mortality in people with HIV/AIDS
- **R** Stavudine, lamivudine and nevirapine combination therapy for treatment of HIV infection and AIDS in adults.
- **R** Three- or four- versus two-drug antiretroviral maintenance regimens for HIV infection
- Single drugs
  - **R** Immediate versus deferred zidovudine (AZT) in asymptomatic or mildly symptomatic HIV infected adults
  - **R** Zidovudine (AZT) versus AZT plus didanosine (ddI) versus AZT plus zalcitabine (ddC) in HIV infected adults
- Structured treatment interruptions
  - **R** Structured treatment interruptions (STI) in chronic suppressed HIV infection in adults
  - **R** Structured treatment interruptions (STI) in chronic unsuppressed HIV infection in adults
- HIV+ children
  - **P** Antiretroviral therapy for HIV-infected children
- ★ **Prophylaxis and treatment of opportunistic infections (OIs)**
  - Prophylaxis
    - **R** Adjunctive corticosteroids for *Pneumocystis jiroveci* pneumonia in patients with HIV-infection

- R Antifungal interventions for the primary prevention of cryptococcal disease in adults with HIV
- R Cotrimoxazole for prophylaxis or treatment of opportunistic infections of HIV/AIDS in patients with previous history of hypersensitivity to cotrimoxazole
- R Cotrimoxazole prophylaxis for opportunistic infections in adults with HIV
- R Cotrimoxazole prophylaxis for opportunistic infections in children with HIV infection
- R Impact of tuberculosis preventive therapy on tuberculosis and mortality in HIV-infected children
- P Interventions for the prevention of mycobacterium avium complex in adults and children with HIV
- R Management of toxoplasmic encephalitis in HIV-infected adults (with an emphasis on resource-poor settings)
- TB
  - P Duration of therapy for tuberculosis in patients infected with Human Immunodeficiency Virus
  - R Treatment of latent tuberculosis infection in HIV infected persons
- Oropharyngeal infections
  - R Interventions for the prevention and management of oropharyngeal candidiasis associated with HIV infection in adults and children
- Cryptosporidiosis
  - R Prevention and treatment of cryptosporidiosis in immunocompromised patients
- ★ **Treatment of Malignancies**
  - R Interventions for Previously Untreated Patients with AIDS-Associated Non Hodgkin's Lymphoma
  - R Interventions for squamous cell carcinoma of the conjunctiva in HIV-infected individuals

→ R Interventions for treating AIDS-associated Hodgkin's lymphoma in treatment-naive adults

→ P Treatment for leiomyosarcoma and leiomyoma in children with HIV infection

→ R Treatment of Kaposi's sarcoma in HIV-1 infected individuals with emphasis on resource poor settings

★ **Immunizations**

→ P Measles/MMR vaccine for infants born to HIV-positive mothers

→ P Pneumococcal vaccine for prevention of Streptococcus pneumoniae infection in HIV infected persons.

★ **Prognostics Markers**

→ P Antiretroviral resistance testing in treatment-naive HIV-infected adults

→ P Genotypic antiretroviral resistance testing at viral failure in people with HIV

→ P Therapeutic drug monitoring of antiretrovirals for people with HIV

★ **Diagnostics Assays**

★ **Complementary Medicine**

→ R Herbal medicines for treating HIV infection and AIDS

→ P The medical use of cannabis for reducing morbidity and mortality in patients with HIV/AIDS

★ **Treatment of other conditions**

→ R Adjunctive therapies for AIDS dementia complex

→ R Antimotility agents for chronic diarrhoea in people with HIV/AIDS

→ P Antiviral agents for treating CMV infection of the nervous system in people with HIV

→ P The effects of antiviral therapy of genital herpes in HIV-infected individuals

→ R Treatment for anemia in people with AIDS

→ R Treatment of acute cryptococcal meningitis in HIV infected adults, with an emphasis on resource-limited settings

- **R** Treatment of helminth co-infection in HIV-1 infected individuals in resource-limited settings.

## **Reviews of Health Services and Care**

### **★ Health care characteristics**

- **P** Interventions for Educating Traditional Healers about STD and HIV Medicine
- **P** Provider training and experience for people living with HIV/AIDS
- **R** Setting and organization of care for persons living with HIV/AIDS

### **★ Quality of life**

- **R** Aerobic exercise interventions for adults living with HIV/AIDS
- **R** Anabolic steroids for the treatment of weight loss in HIV-infected individuals
- **P** Cognitive behavioural therapy (CBT) for adults with HIV
- **P** Family support in reducing morbidity and mortality in HIV-infected persons
- **P** Home-based care for reducing morbidity and mortality in people infected with HIV/AIDS
- **R** Iron supplementation for reducing morbidity and mortality in children with HIV
- **P** Massage therapy for people with HIV/AIDS
- **R** Micronutrient supplementation in children and adults with HIV infection
- **R** Nutritional interventions for reducing morbidity and mortality in people with HIV
- **R** Progressive resistive exercise interventions for adults living with HIV/AIDS

### **★ Treatment adherence**

- **R** Patient support and education for promoting adherence to highly active antiretroviral therapy for HIV/AIDS
- **P** Substitution of nurses for doctors in managing HIV/AIDS antiretroviral therapy