平成26-27年度厚生労働科学研究費補助金
地域医療基盤開発推進研究事業

安全な薬物治療を促進する多職種間情報共有システムの開発に関する研究

平成27年度　研究班会議

研究代表者

兵庫医科大学

森本　剛

平成28年3月10日　　フクラシア東京ステーション

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議事

1. 挨拶・出席者紹介　（森本）
2. 研究の背景及び計画　（森本）
3. 薬剤性有害事象の臨床疫学　（太田）
4. 腎機能介入による適正処方率への影響　（園山）
5. 腎機能介入によるアウトカム評価　（森本）
6. 下痢アラートによるアウトカム評価　（作間）
7. 医師を対象とした横断調査によるシステム評価①　（中村）
8. 医師を対象とした横断調査によるシステム評価②　（湯坐）
9. 多職種を通じた医薬品のリスク最小化活動　（岡本）
10. 研究の総括と次への課題　（森本）
11. 総合討論

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研究班構成・出席予定者

担当官庁
厚生労働省　医政局総務課　医療安全推進室
草間　直子　先生

- 研究代表者
  - 森本　剛
- 分担研究者
  - 作間　未織
  - 太田　好紀
  - 湯坐　有希
- 研究協力者
  - 中村　嗣
  - 園山　智宏
  - 岡本　里香
- 研究事務局
  - 青木　美緒
  - 岩元　有加

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研究の背景及び計画

兵庫医科大学

森本　剛

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薬剤性有害事象のリスク

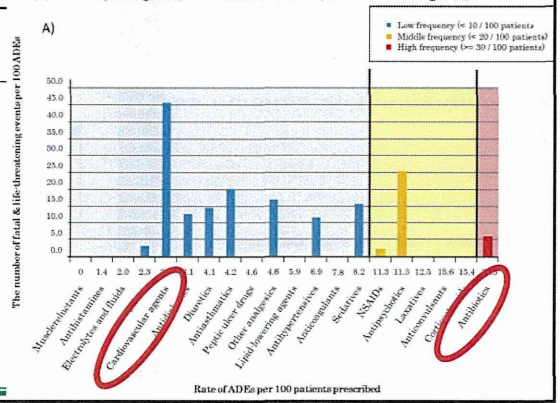
Table 1. Incidence of Adverse Drug Events

Ward	n	Patient-days	ADEs	Incidence*	95% CI	Crude rate†	95% CI	Annual ADEs‡
Medicine	1,531	25,734	504	19.6	17.9-21.3	32.9	30.6-35.3	4,148
Surgery	1,469	30,419	407	13.4	12.1-14.7	27.7	25.4-30.0	3,218
ICU	459	3,230	99	30.7	24.6-36.7	21.6	17.8-25.3	634

*ADE, adverse drug event; ICU, intensive care unit; CI, confidence interval; *per 1,000 patient-days; †per 1,000 admissions; ‡Extrapolated from number of ADEs and information from three hospitals.*

Table 5. Stages of Primary Errors Associated with Preventable and Potential Adverse Drug Events

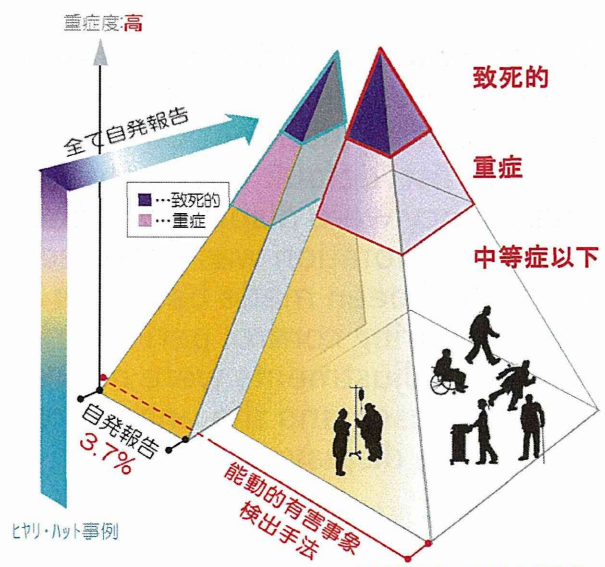
Event	Ordering n (%)	Transcription n (%)	Dispensing n (%)	Administration n (%)	Monitoring n (%)
Preventable ADEs	49 (35)	0 (0)			
Intercepted potential ADEs	88 (90)	0 (0)			
Nonintercepted potential ADEs	182 (76)	2 (0.8)			
All above events	319 (66)	2 (0.4)			



- ✓ 100患者あたり29件の薬剤性有害事象
- ✓ エラーの過半数は医師のオーダー段階
- ✓ 薬剤種別ごとに、頻度及び重症度のデータ

（Morimoto T. ***J Gen Intern Med*** 2011; Sakuma M. ***J Patient Saf*** 2015）

一部しか認識されていない



致死的 6.5%

重症 33%

中等症以下 61%

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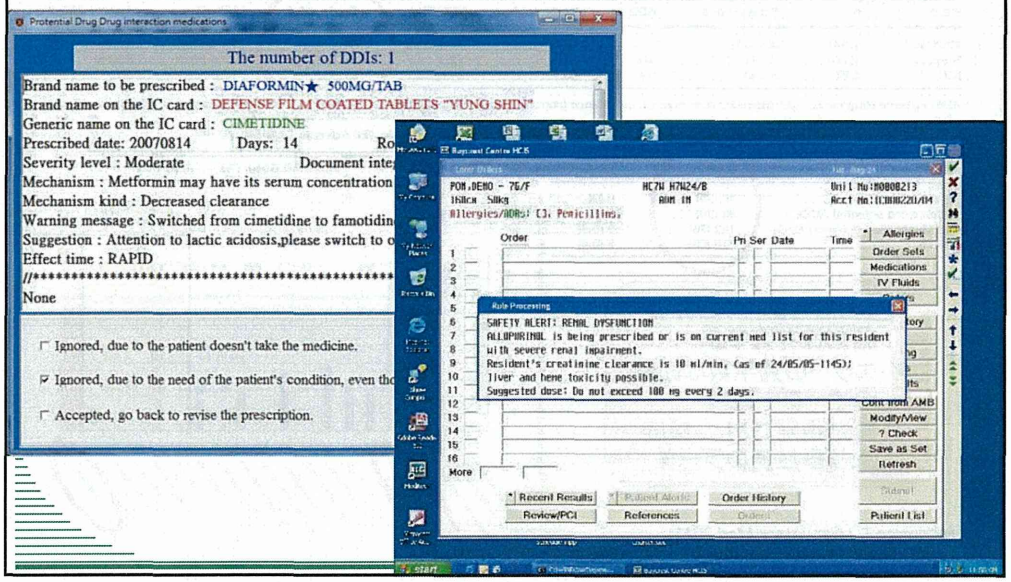
一つの方略

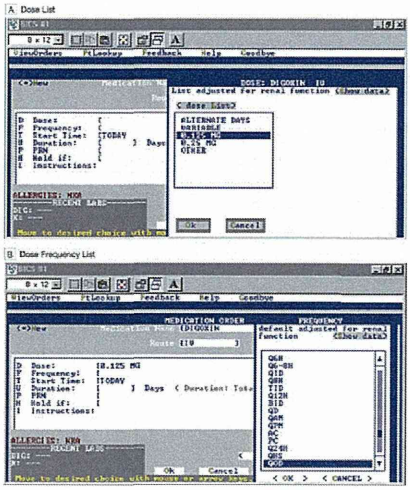
Brigham Integrated Computing System (BICS)　1984～



JAMA 2001;286:2839-44

Guided medication dosing for inpatients with renal insufficiency

- **Real-time computerized decision support system** for prescribing drugs in patients with renal insufficiency. During intervention periods, the **adjusted dose list**, default dose amount, and default frequency were displayed to the order-entry user and a notation was provided that adjustments had been made **based on renal insufficiency**. During control periods, these recommended adjustments were not revealed to the order-entry user, and the unadjusted parameters were displayed.



The JAMA Network

From: **Guided Medication Dosing for Inpatients With Renal Insufficiency**

JAMA. 2001;286(22):2839-2844. doi:10.1001/jama.286.22.2839

Table 2. Rates of Appropriate and Inappropriate Orders in Intervention vs Control Periods*

	All Orders With Dose or Frequency Alteration			Dose Alteration			Frequency Alteration		
	Intervention	Control	*P* Value‡	Intervention	Control	*P* Value‡	Intervention	Control	*P* Value‡
Inappropriate†	2714 (49)	6298 (70)	<.001	1211 (33)	2743 (46)	<.001	1689 (41)	4456 (65)	<.001
Appropriate	2776 (51)	2652 (30)		2478 (67)	3221 (54)		2447 (59)	2358 (35)	
Total	**5490**	**8950**		**3689**	**5964**		**4136**	**6814**	

*Values expressed as number (percentage).
†Defined as an excessive dose (higher than recommended) or frequency (more frequent than recommended).
‡χ^2 Test of proportions.

Date of download: 3/7/2016

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The JAMA Network

From: **Guided Medication Dosing for Inpatients With Renal Insufficiency**

JAMA. 2001;286(22):2839-2844. doi:10.1001/jama.286.22.2839

Table 3. Unadjusted Length of Stay and Costs in Intervention and Control Periods*

	Without Overlapping Admissions†			With Overlapping Admissions†		
	Intervention	Control	*P* Value	Intervention	Control	*P* Value
Length of stay, mean (SD), d‡	4.3 (4.5)	4.5 (4.8)	.009	5.3 (7.1)	5.4 (7.4)	.05
Total costs, $	4881 (2974-9383)	4968 (3035-9590)	.52	5211 (3093-10 497)	5282 (3156-10 570)	.51
Pharmacy costs, $	168 (77-417)	166 (79-416)	.64	185 (82-497)	179 (83-479)	.45

*Values presented as median (interquartile range) unless otherwise indicated.
†An overlapping admission is defined as an admission spanning across intervention and control periods. For the purpose of the comparison, the admission was assigned to the group (intervention vs control) active on the first admission day.
‡Median (interquartile range) for intervention and control is 3 (2-5), although Wilcoxon rank-sum tests are significant due to differences in distribution.

腎機能は変化なし

- **A 10-mL/min (0.17-mL/s) decrement in estimated creatinine clearance from admission to discharge** was considered to be of clinical significance. The percentage of patients whose estimated creatinine clearance declined by more than 10 mL/min (0.17 mL/s) was **11.8%** and **11.5% (intervention vs control, P = .43)**. The **mean (SD) changes in estimated creatinine clearance** were **1.9 (0.2)** mL/min (0.03 [0.003] mL/s) and **2.3 (0.2)** mL/min (0.04 [0.003] mL/s) during the corresponding periods **(P = .18)**.

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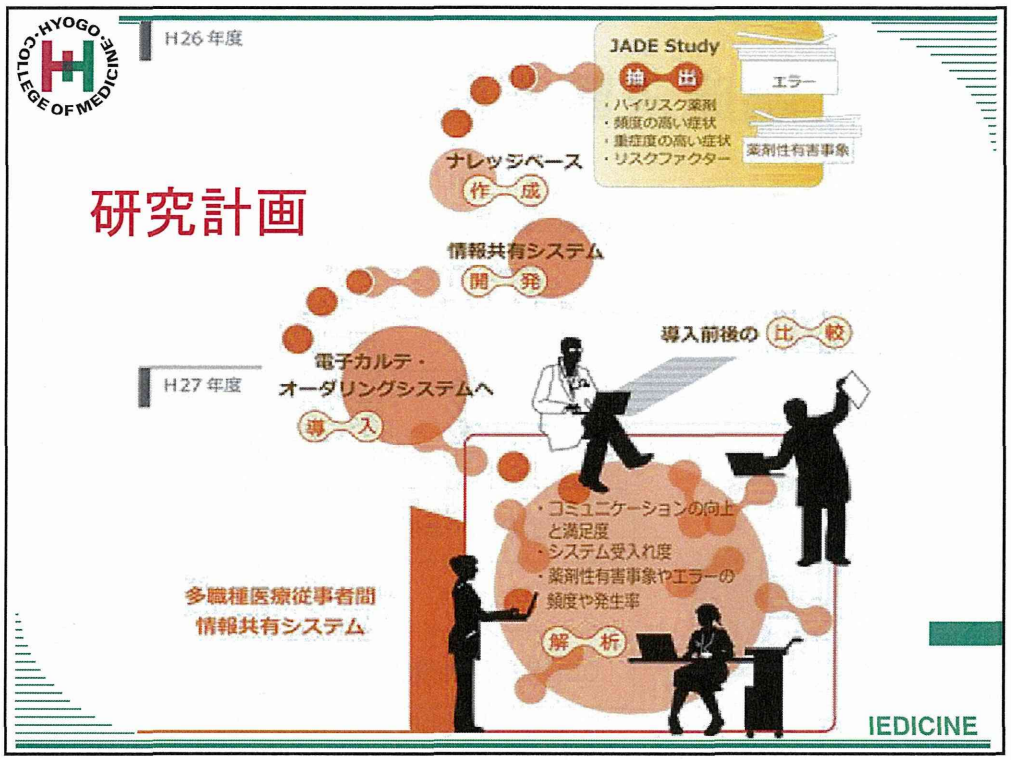

JADE Study - Intervention

- 研究デザイン
  - 前向きコホート研究（ヒストリカル対照）
  - IRB承認
- 対象
  - 市中総合病院に入院した15歳以上の患者すべて
- 臨床決断支援システム
  - 腎機能に応じた処方ガイド
  - 抗菌薬投与患者における下痢アラート
- アウトカム
  - 入院期間中の腎機能の変化
  - 入院中の下痢イベントの頻度

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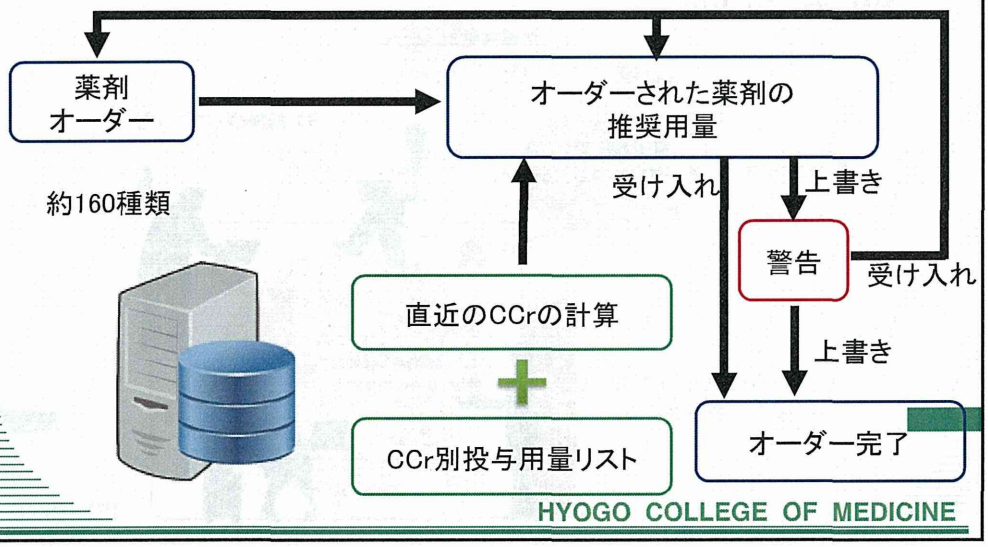
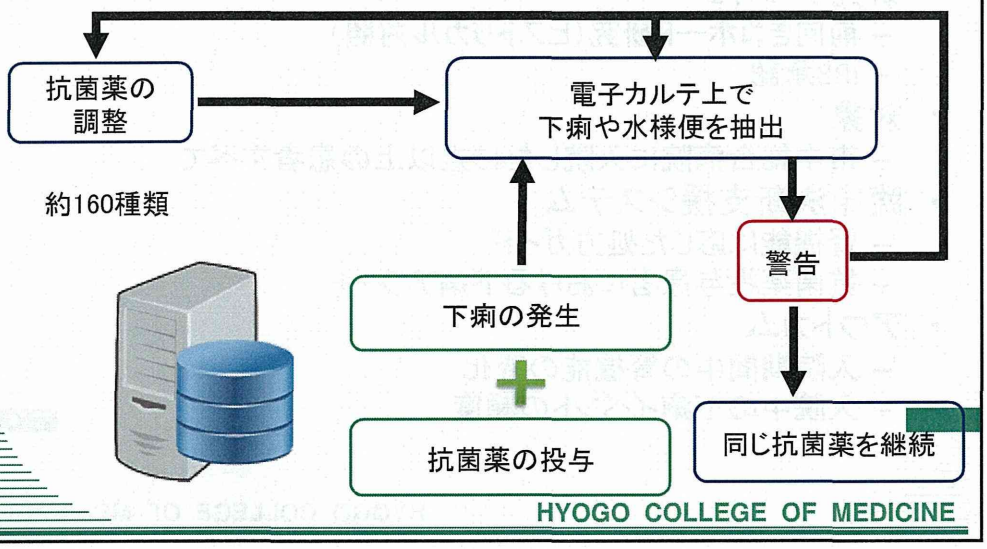
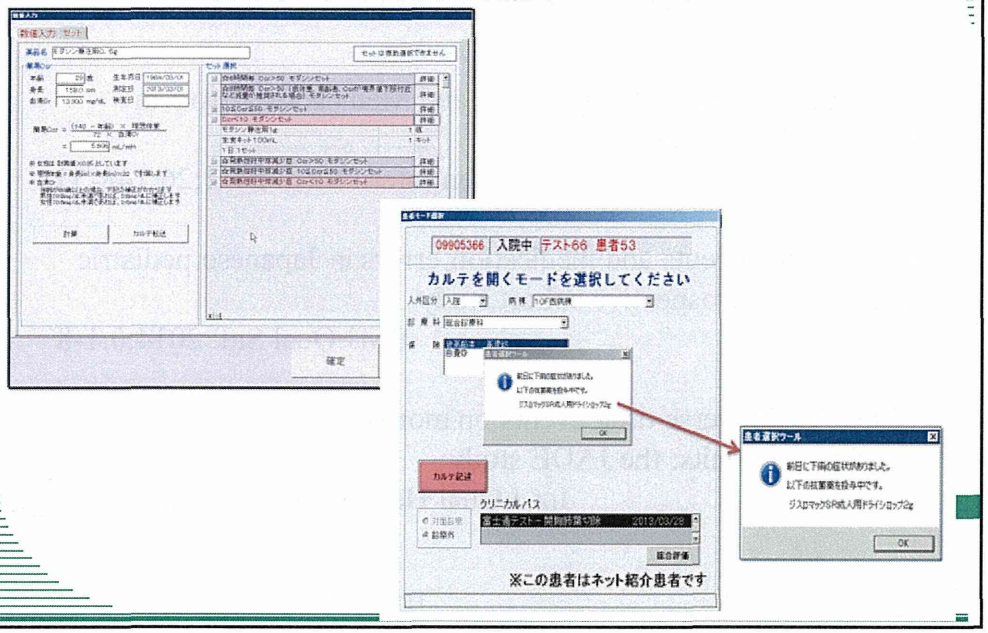
臨床決断支援システム



臨床決断支援システム



臨床決断支援システム



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太田好紀

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Adverse Drug Events in Japan: JADE study

Incidence of Adverse Drug Events and Medication Errors in Japan: the JADE study

J Gen Intern Med. 2011;26:148-53

Adverse drug events and medication errors in Japanese pediatric inpatients: a retrospective cohort study

BMJ Qual Saf. 2014;0:1-8

Influence of adverse drug events on morbidity and mortality in intensive care units: the JADE study

Int J Qual Health Care. 2014;26:573-8

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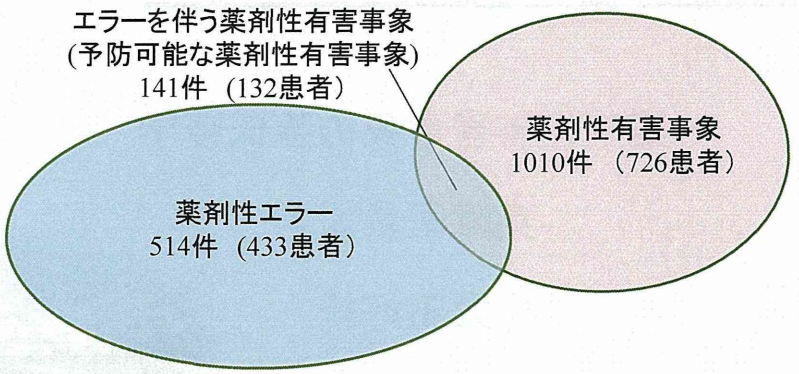
成人患者における薬剤性有害事象

対象：2004年1月から6月の期間、3施設の15歳以上の全ての入院患者

結果：3459患者、59383患者日



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