發揮醫檢師的價值：快速且準確診斷困難梭狀桿菌，降低該菌株造成的院內感染

馬偕紀念醫院 台北與淡水院區

感染管制中心

張富傑 感染管制醫檢師

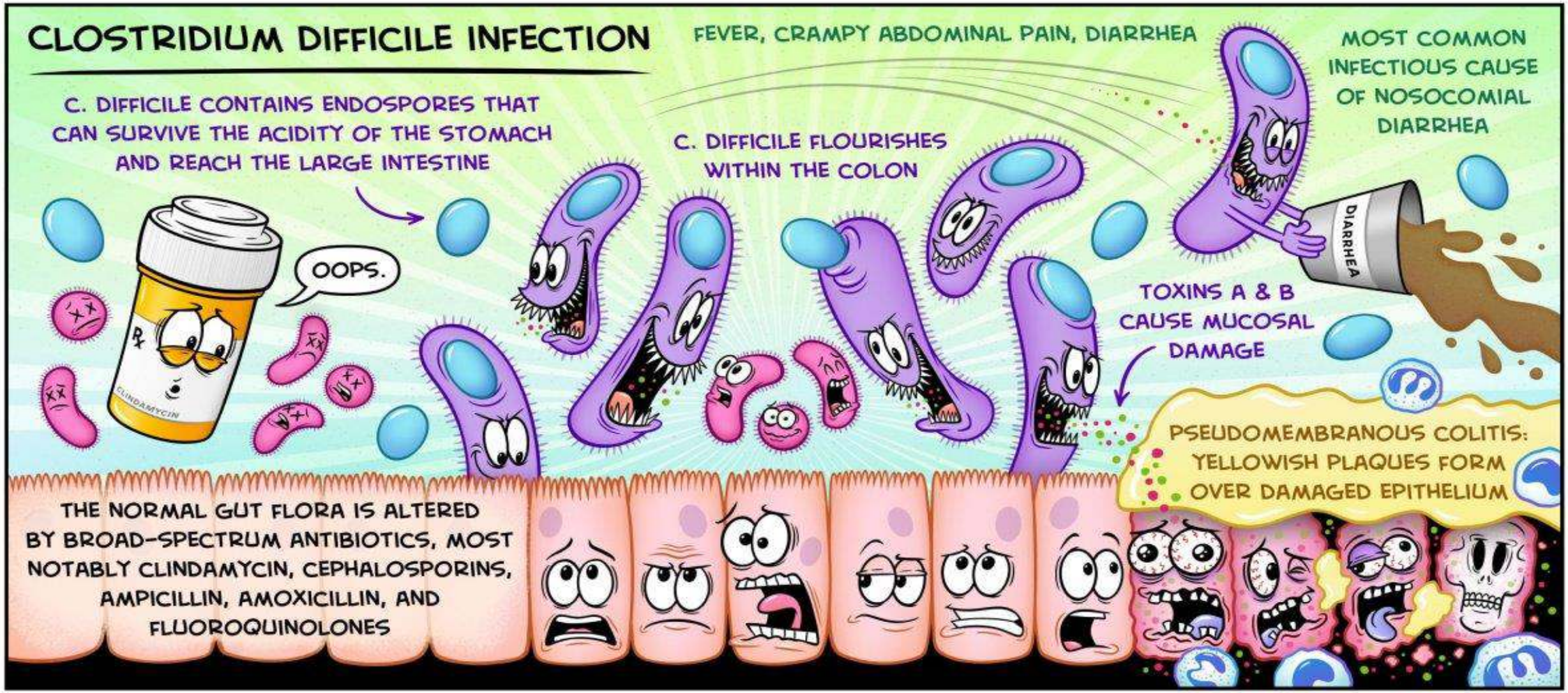
佛系醫檢師

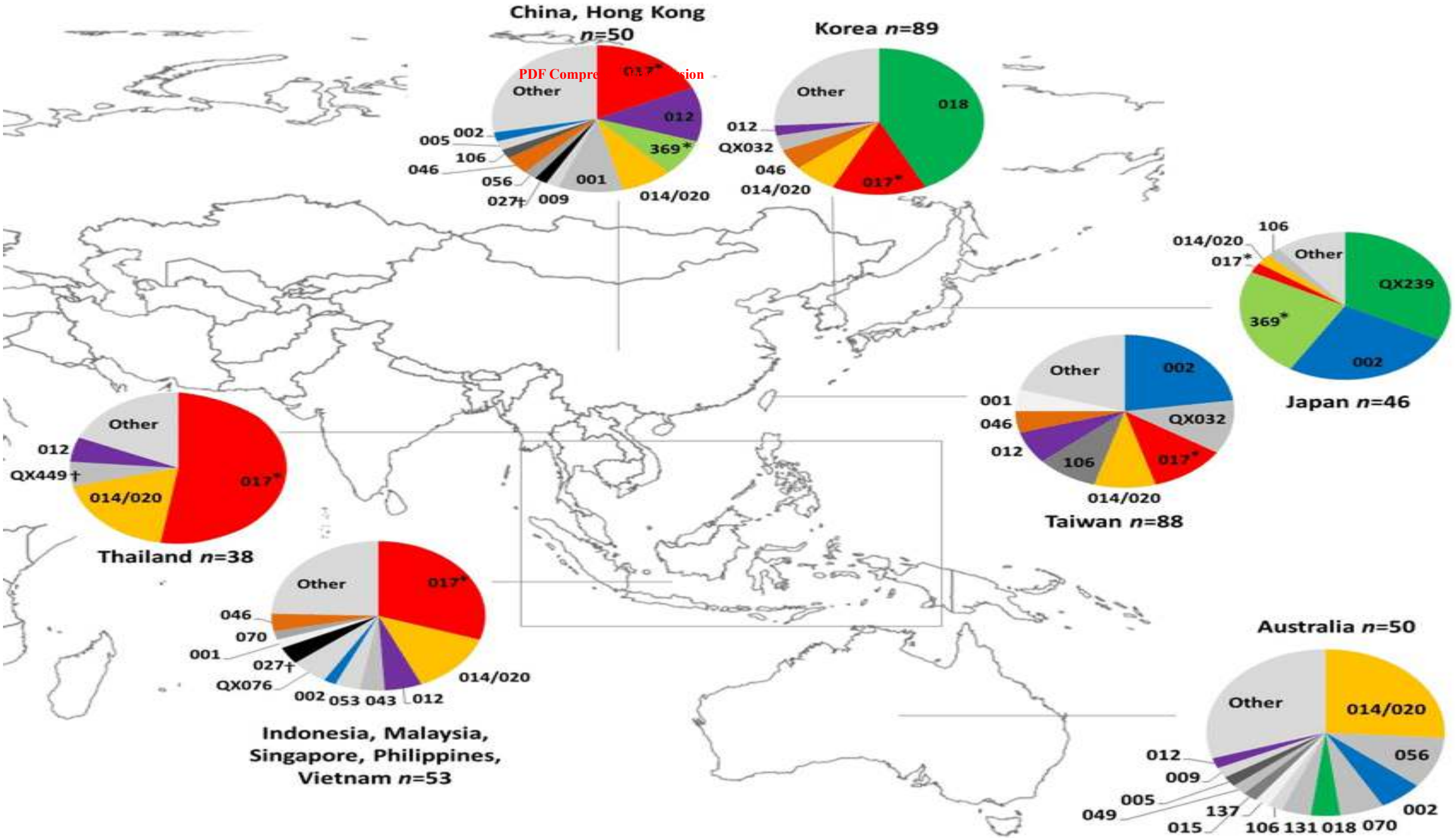
實際上的醫檢師

走歪的醫檢師–感染管制醫檢師

[感控醫檢師]
醫院的空氣、飲用水、自來水、醫療器材，法定傳染病的控制，甚至是美食街的餐點，都要確保絕對的安全，避免病患的病情加重，也收穫來往醫院人員的安全。
感控醫檢師，在醫院扮演者地下守護神的角色。工作除了法定傳染病的確認、通報，醫院的大感染也需要感控醫檢師來檢驗，手術室的無菌管理、飲用水的生菌數等等。
感控醫檢師也有特別的證照，需要在感染管制協會以及相關教學醫院受訓，考試通過後才能取得證照。醫檢、護理背景都可以參加。
#醫檢師 #感控 #感控醫檢師

Clostridium difficile




China, Hong Kong
n=50
Other
017*
012
369*
001
014/020
027†
009
056
046
106
005
002
Korea n=89
Other
018
012
QX032
046
014/020
017*
Japan n=46
Other
QX239
002
369*
017*
014/020
106
Taiwan n=88
Other
002
QX032
017*
106
014/020
012
046
001
Thailand n=38
Other
017*
014/020
012
QX449†
Indonesia, Malaysia,
Singapore, Philippines,
Vietnam n=53
Other
017*
014/020
012
043
053
002
QX076
027†
001
070
046
Australia n=50
Other
014/020
056
002
106
131
018
070
137
015
049
005
009
012

DEADLY DIARRHEA:

C. DIFFICILE CAUSES IMMENSE SUFFERING, DEATH

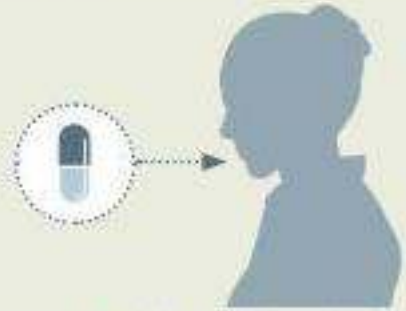
IMPACT

Caused close to half a million illnesses in one year.

Comes back at least once in about 1 in 5 patients who get *C. difficile*.

1 in 11 people 65 and older died within a month of *C. difficile* infection diagnosis.

RISK



People on antibiotics are 7-10 times more likely to get *C. difficile* while on the drugs and during the month after.

Being in healthcare settings, especially hospitals or nursing homes.

More than 80% of *C. difficile* deaths occurred in people 65 and older.

Bundles for Prevention of C. difficile Infection (CDI)

Antimicrobial and Drug Management Bundle

- Evidence-based management and treatment
- Judicious use of all antibiotics
- Robust A.S. program led by pharmacy and physician champion (ex, hospitalist)
- Assess use of probiotics
- Assess use of proton pump inhibitors
- Educate providers and patients

Detection Bundle

- Early Recognition: Simple Diagnosis
- Testing criteria
- Proper collection and handling of specimens (timeframe and temperature)
- Appropriate testing
  - PCR
  - Antigen/toxin assay
- Retesting criteria
  - No testing for cure

Cleaning Bundle

- Environment
- Equipment
  - ID C. diff contaminated equipment for cleaning
- Daily cleaning
- Terminal cleaning
- Use of checklist
- Appropriate dwell time for cleaning solutions
- Competency assessment

Practice Bundle

- Early isolation
- Contact Precautions
  - Gowns
  - Gloves
  - Signage
  - Hand Hygiene with soap and water
- Equipment
  - Available
  - Dedicated
  - Disposable
  - Disinfected if reusable

People Bundle

- Administrative support
- Competency
- Compliance
- Coach
- Communicate
- Involve and educate patients/ families
- Educate all staff
- Collaborative efforts beyond the hospital

SPREAD

Touching unclean surfaces, especially those in healthcare settings, contaminated with feces from an infected person.

Dirty hands.

Failing to notify other healthcare facilities when patients with *C. difficile* transfer from one facility to another.

PREVENT

Improve prescribing of antibiotics.

Use best tests for accurate results to prevent spread.

Rapidly identify and isolate patients with *C. difficile*.

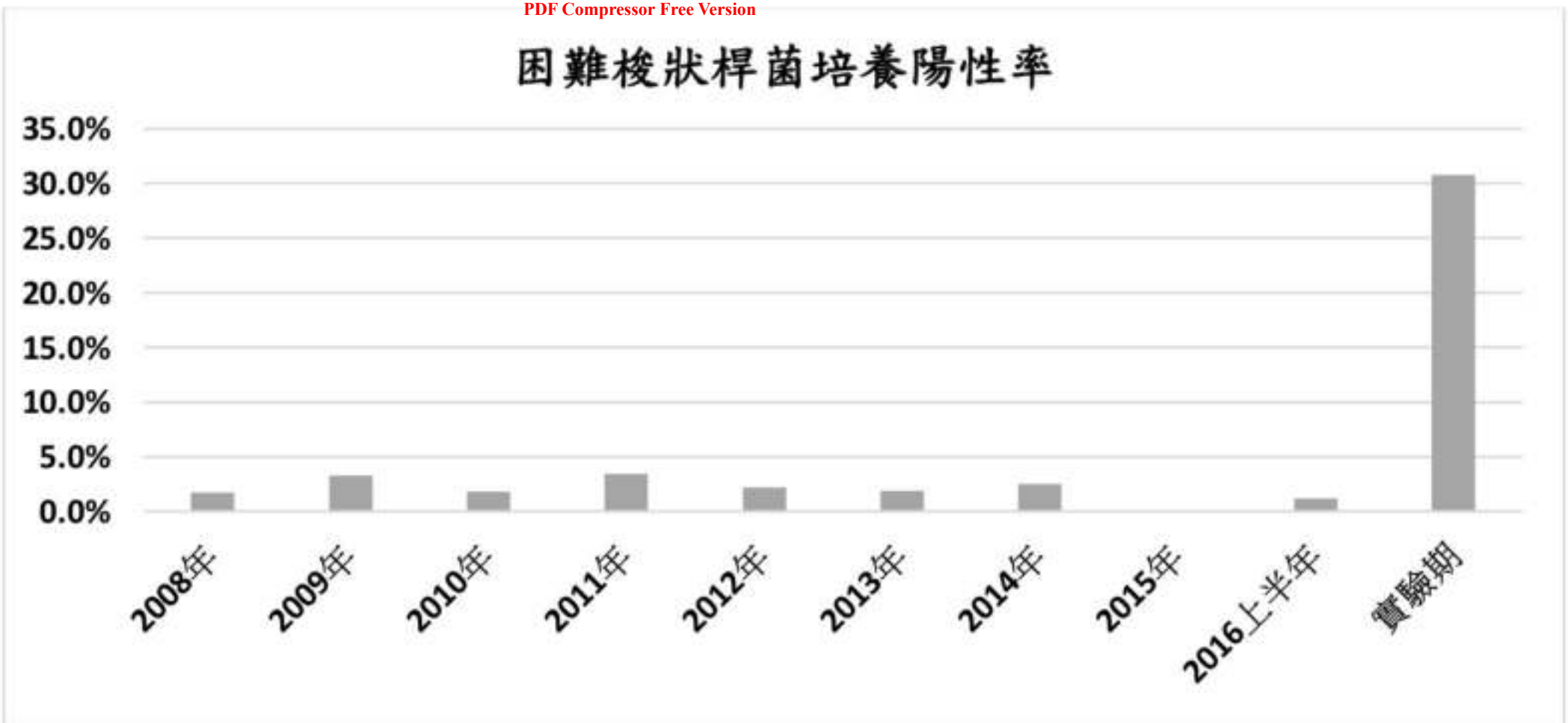
Wear gloves and gowns when treating patient with *C. difficile*. Remember that hand sanitizer doesn't kill *C. difficile*.

Clean room surfaces with EPA-approved, spore-killing disinfectant (such as bleach), where *C. difficile* patients are treated.

http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_infect.html

www.cdc.gov/media

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

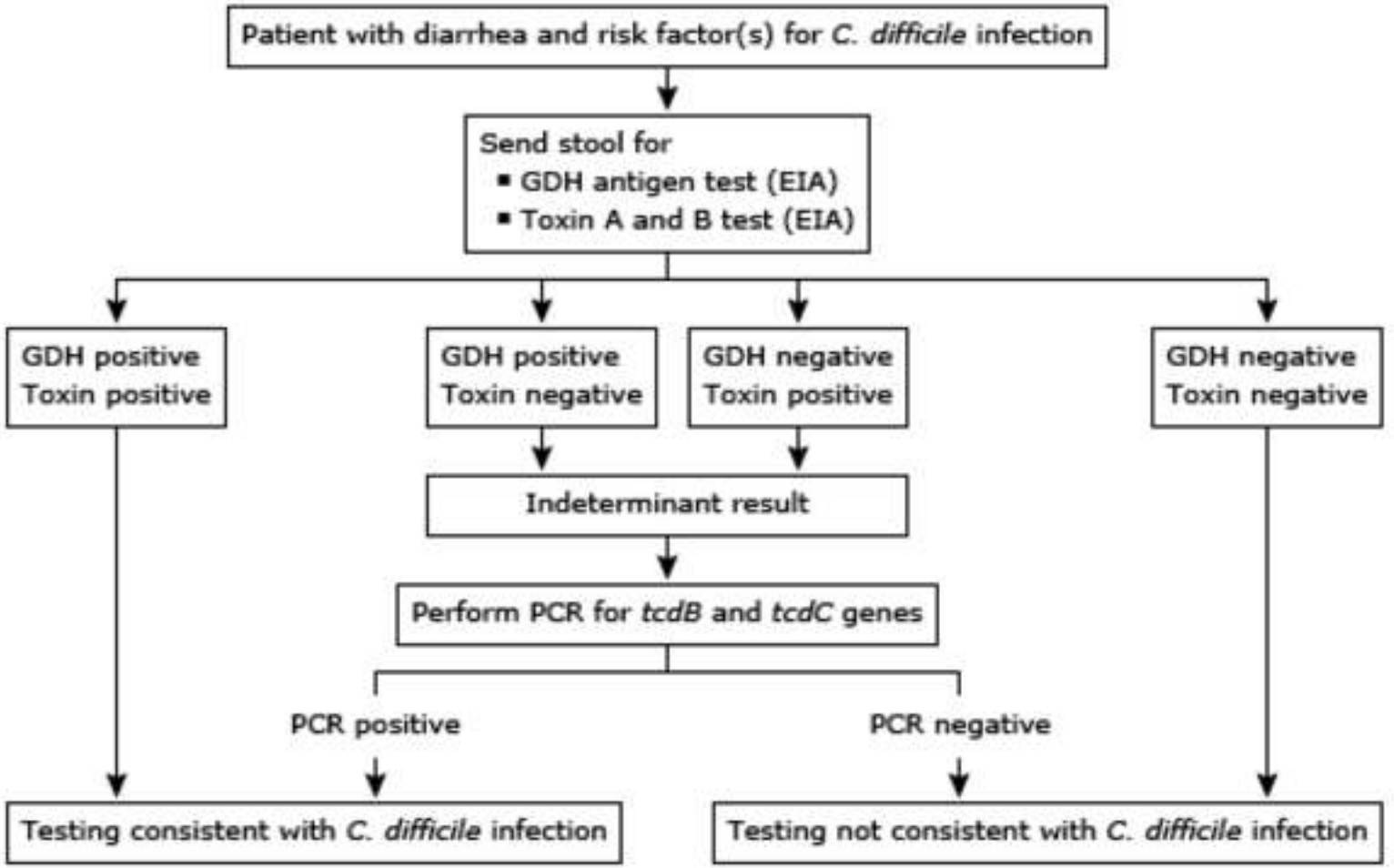


▲(圖一)本院困難梭狀桿菌的培養陽性率，可以看到在實驗期的時候，困難梭狀桿菌的培養陽性率高於過往。

Table 1. Diagnostic Tests for Toxigenic *Clostridium difficile*[a]

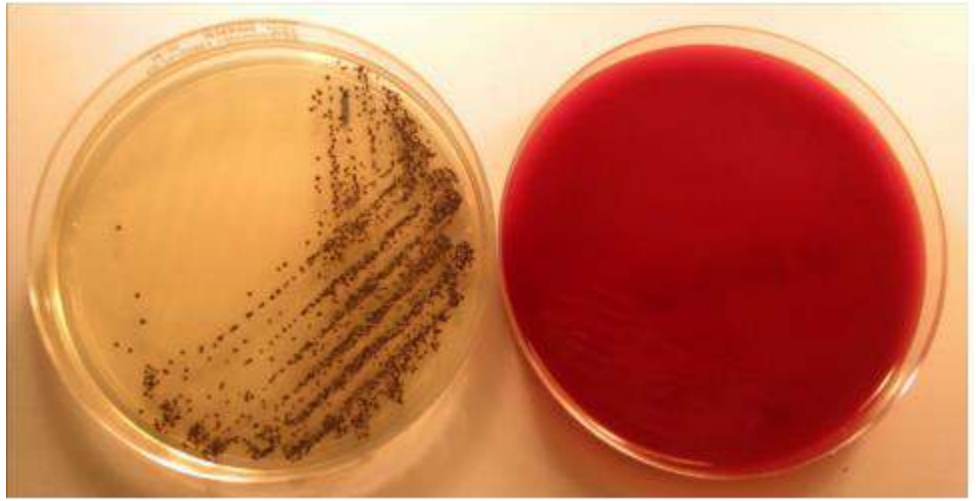
Tests by Type and Method	Target(s)	Characteristics
Gold standards		
Toxigenic culture	Toxigenic *C difficile*	Reference standard Difficult to perform Time consuming (24-48 h)
Cell cytotoxicity assay	Toxins A or B[b]	Reference standard Highly sensitive for toxin compared with EIA Difficult to perform Time consuming (24-48 h)
Rapid diagnostic tests		
EIA	GDH	GDH alone insufficient for diagnosis (must be paired with a test for toxin) Rapid Variable sensitivity and specificity
EIA	Toxins A or B[b]	Rapid Variable sensitivity and specificity
NAAT		Rapid but more expensive than EIA Highly sensitive and specific for presence of toxigenic *C difficile* May increase detection of colonization and not true CDI
RT-PCR	*tcdB* or *tcdC* genes	*tcdA*-negative/*tcdB*-positive strains can cause disease
LAMP	*tcdA* or *tcdB* genes	*tcdA*-positive/*tcdB*-negative not well described in human disease Caution required in interpreting negative results based on *tcdA* testing alone by LAMP

Approach to diagnosis of *Clostridium difficile*



TEST	SENSITIVITY (%)	SPECIFICITY (%)	COMMENT
Cell cytotoxicity	77-86	97-99	Less sensitive of two "gold standards" compared with toxigenic culture
Toxigenic culture for *C. difficile*	95-100	96-100	The more sensitive of two "gold standards"

gold standards
→discovery of
C. difficile + toxins



Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases, 8th ed.

TEST	SENSITIVITY (%)	SPECIFICITY (%)	COMMENT
EIA for toxins A and B	67-92 60-89	93-99 93-99	Versus cell cytotoxicity Versus toxigenic culture
EIA for GDH	71-100	67-99	Compared with stool culture for *C. difficile*
Nucleic acid amplification test (PCR and LAMP)	88-100	88-97	Most sensitive rapid single test available but also most expensive
Two-step GDH Three-step GDH testing	56-90 83-100	81-97 93-100	Discrepancy between GDH and toxin test is 13%-19%.

Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases, 8th ed.

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Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases, 8th ed.

2013 Annual Report for the Emerging Infections Program for *Clostridium difficile* Infection

In 2013, a total of 16,379 cases of *C. difficile* infection (CDI) were reported to the Emerging Infections Program (EIP) in 36 counties in 10 US states (California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee).

Table 1. Reported Number of CDI Cases and Crude Incidence by Sex, Age Group, Race, and Epidemiologic Classification[a]

Demographic Characteristic	Population ≥1 Year of Age	Community Associated CDI		Healthcare Associated CDI		All CDI	
		No.	Incidence[b]	No.	Incidence[b]	No.	Incidence[b]
Sex							
Male	5663849	2401	42.39	4308	76.06	6709	118.45
Female	5889106	4040	68.60	5630	95.60	9670	164.20
Age group							
1-17 years	2546460	494	19.40	193	7.58	687	26.98
18-44 years	4549306	1592	34.99	983	21.61	2575	56.60
45-64 years	3040854	2063	67.84	2546	83.73	4609	151.57
≥65 years	1416335	2292	161.83	6216	438.88	8508	600.71
Race							
White	8033940	5255	65.41	7611	94.74	12866	160.15
Non-white	3519015	1186	33.70	2327	66.13	3513	99.83
Total	11552955	6441	55.75	9938	86.02	16379	141.77

[a] The epidemiologic classification was statistically imputed for 0.6% of the observed CDI cases, and race was statistically imputed for 21.8% of the observed CDI cases. The weighted frequency of cases in Colorado and Georgia were based on 33% random sampling.

[b] Cases per 100,000 persons.

台灣住院病人艱難梭狀桿菌感染發生率

臺大醫院[1,3]/成大醫院[2]/衛福部南醫[4]

Case No. (%); case/100,000 patient-days (NTUH[1]/ NCKUH[2]/ NTUH[3] /MOHWTH[4])

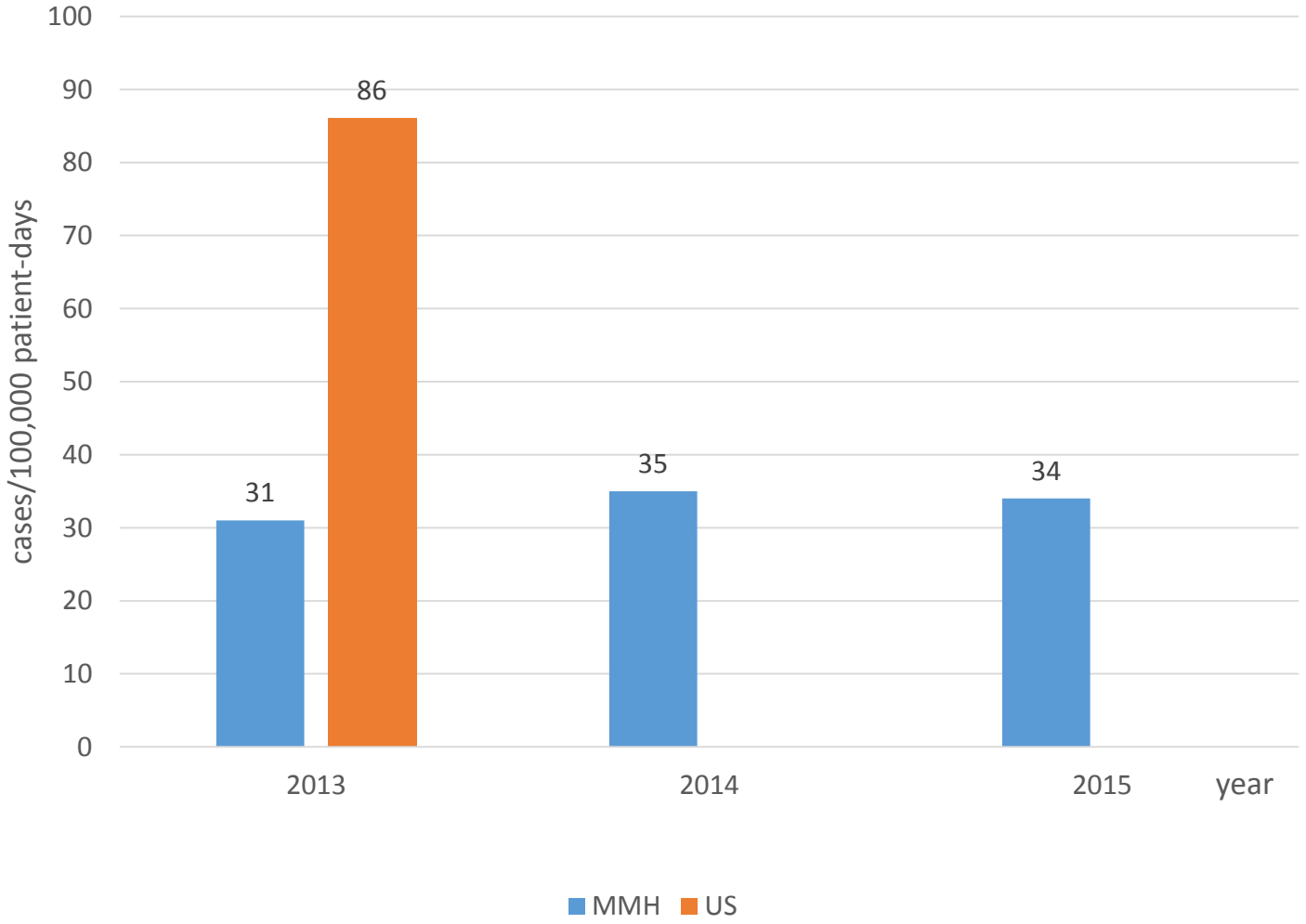
	2006	/2010	/2012	/2013
Medical ICUs - 23 (22.1); 110.6 / 790				
Oncology wards - 29 (33.7); 66.7 / 42				
Infection ward - 10 (11.6); 105.0 / 18				
Nephrology ward - 8 (9.3); 59.4				
Gastrointestinal ward - 6 (7.0); 25.1				
Other medical wards - 10 (11.6); 12.0				

Overall – 101.2/42.6/45/42.4 per 100,000 patient-days
(3.4 cases/29.0 per 1,000 discharges)

***53.8 cases/100,000 patient-days in a large teaching hospital in Singapore, 2003**
- Pathology 2007;39:438–42

J Microbiol Immunol Infect 2006:38:242-8[1]; 2010;43:119-25[2]; 2012;45:287-95[3]
PLos One 2013;8(7):e69577[4]

MMH Nosocominal Incidence of CDI



MMH 2014 C. difficile infection

- 672 cases Toxin rapid test and culture
- Culture positive rate: 46/672
- Toxin positive rate: 153/672
- Toxin positive cases, culture positive rate: 38/153= 24.8%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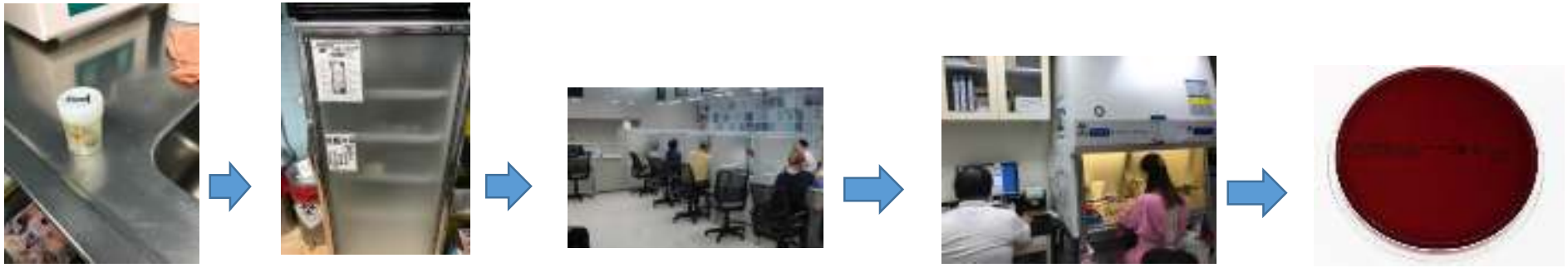
面對問題是解決問題的第一步

Why

- 臨床檢體運送流程
- 病房採檢->儲存->傳護送->檢驗櫃檯->細菌室收件->**culture medium**



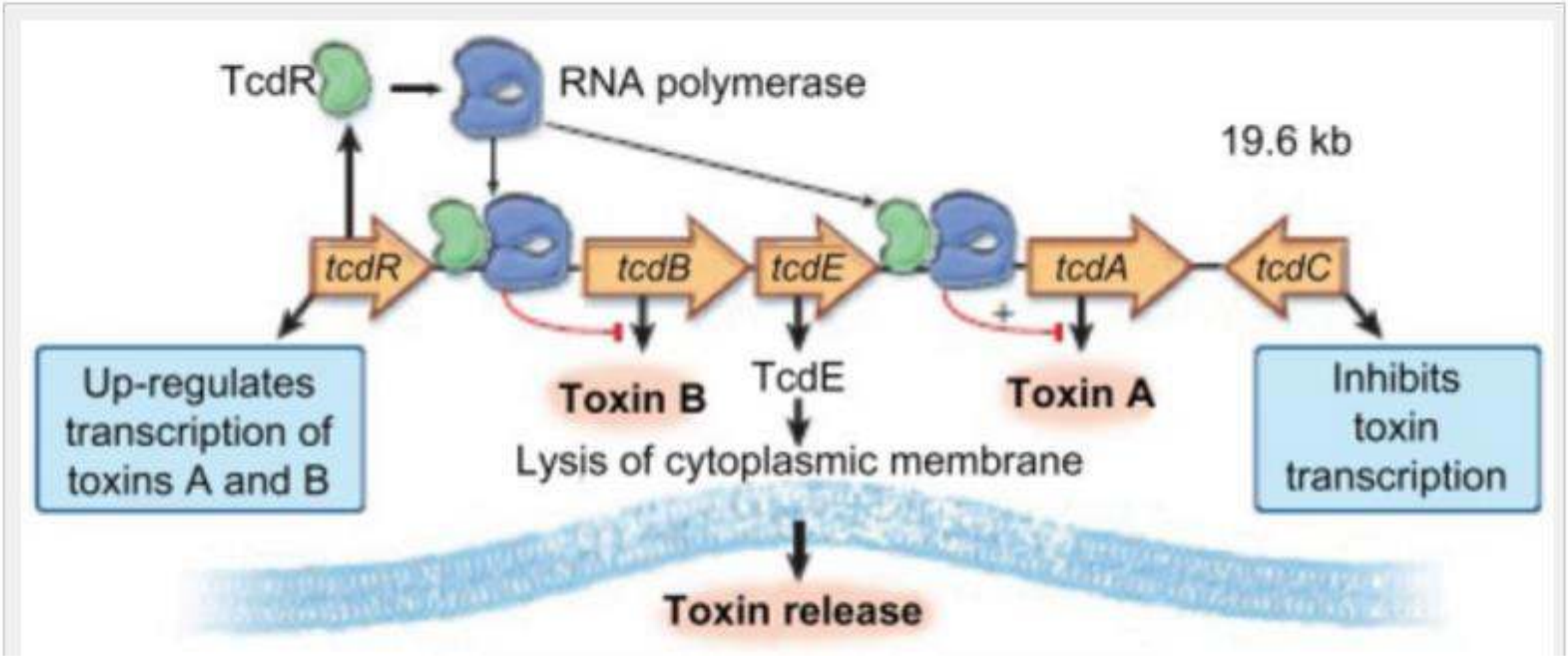
Why

- 厭氧箱設定

本院厭氧陽性率平均約10%~15%，但是當機器部穩定時，陽性率約為7%~12%(檢驗科整建後)

Why

- Toxin 偽陽性問題 (殘影，造成結果誤判)



Clostridium difficile outbreaks: prevention and treatment strategies.
Martinez FJ, Leffler DA, Kelly CP - Risk Manag Healthc Policy (2012)

解決方法 1.

1. 改善臨床檢體運送流程

1) 檢體30分鐘內送至檢驗科，2小時內執行檢體接種
2) 泡製95% EtOH

Reller ME, Lema CA, Perl TM, Cai M, Ross TL, Speck KA, Carroll KC. 2007. Yield of stool culture with isolate toxin testing versus a two-step algorithm including stool toxin testing for detection of toxigenic Clostridium difficile. J. Clin. Microbiol. 45:3601–3605.

解決方法 2.

- **新增GDH檢驗項次**

TEST	SENSITIVITY (%)	SPECIFICITY (%)	COMMENT
Two-step GDH Three-step GDH testing	56-90 83-100	81-97 93-100	Discrepancy between GDH and toxin test is 13%-19%.

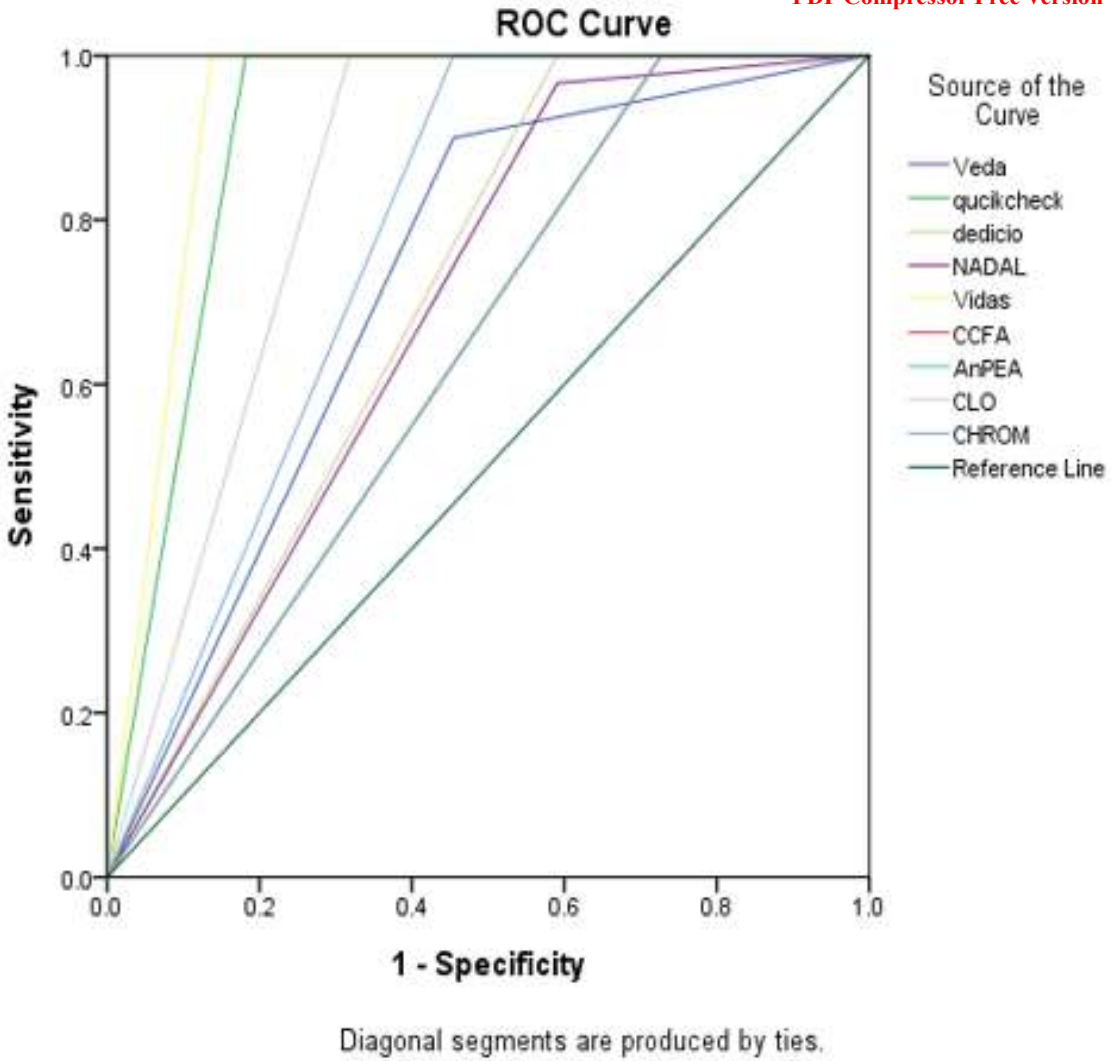
Diagnostic method	True positive	False positive	False negative	True negative	Sensitivity(%)	Specificity(%)	Predict value		Youden Index (%)
							Positive(%)	Negative(%)	
Veda	12	3	10	27	54.5	90.0	80.0	73	44.5
QUIK CHEK	18	0	4	30	81.8	100	100	88.2	81.8
dedicio	9	0	13	30	40.9	100	100	69.8	40.9
NADAL	9	1	13	29	40.9	96.7	90	69	37.6
*VIDAS	19	0	3	30	86.4	100	100	90	86.4

* ELISA

Table 3. Comparing of culture medium in *C. difficile* growth

Diagnostic method	True positive	False positive	False negative	True negative	Sensitivity(%)	Specificity(%)	Predict value		Youden Index (%)
							Positive(%)	Negative(%)	
CCFA	6	0	16	30	27.3	100	100	65.2	27.3
AnPEA	6	0	16	30	27.3	100	100	65.2	27.3
CLO agar	15	0	7	30	68.2	100	100	81.1	68.2
Chrom	12	0	10	30	54.5	100	100	75	54.5

(Fig.1) The ROC curve of all examination



Diagonal segments are produced by ties.

Area Under the Curve

Test Result Variable(s)	Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval Lower Bound	Asymptotic 95% Confidence Interval Upper Bound
Veda	0.723	0.075	0.006	0.575	0.870
qucikcheck	0.909	0.050	0.000	0.811	1.000
dedicio	0.705	0.078	0.012	0.552	0.857
NADAL	0.688	0.079	0.022	0.534	0.842
Vidas	0.932	0.044	0.000	0.846	1.000
CCFA	0.636	0.081	0.096	0.477	0.796
AnPEA	0.636	0.081	0.096	0.477	0.796
CLO	0.841	0.063	0.000	0.717	0.965
CHROM	0.773	0.072	0.001	0.631	0.914

The test result variable(s): Veda, qucikcheck, dedicio, NADAL, Vidas, CCFA, AnPEA, CLO, CHROM has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

▲(圖二)本院困難縮狀桿菌的感染率，在本計畫執行前，約為每十萬分之三十人上下，在本實驗中，改善了診斷方法，所以感染率在實驗初期為每十萬分之85人，實驗中期為每十萬分之七十二人，最後實驗的後期，感染率為每十萬分之五十四。

曾御慈 醫師

/ 1980 - 2013 /

我們來到這世界，就是擁有生命，就應踏實的走向目標。

最重要的：盡其所能。盡其所能地使生命充實，盡其所能地在生命裡幫助那些需要生命的人。