

從法律的角度看SDM

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醫病關係

委任？

承攬？

僱傭？



醫院和醫師的法律關係
是

僱傭關係

專業自主 vs 僱傭
醫病共享 vs 僱傭



知情同意的法源

■ 醫療法

- 第63條

- 醫療機構實施手術，應向病人或其法定代理人、配偶、親屬或關係人說明手術原因、手術成功率或可能發生之併發症及危險，並經其同意，簽具手術同意書及麻醉同意書，始得為之。但情況緊急者，不在此限。
- 前項同意書之簽具，病人為未成年人或無法親自簽具者，得由其法定代理人、配偶、親屬或關係人簽具。
- 第一項手術同意書及麻醉同意書格式，由中央主管機關定之。

知情同意的法源

■ 醫療法

- 第64條

- 醫療機構實施中央主管機關規定之侵入性檢查或治療，應向病人或其法定代理人、配偶、親屬或關係人說明，並經其同意，簽具同意書後，始得為之。但情況緊急者，不在此限。
- 前項同意書之簽具，病人為未成年人或無法親自簽具者，得由其法定代理人、配偶、親屬或關係人簽具。

知情同意的法源

■ 醫療法

- 第79條

- 醫療機構施行人體試驗時，應善盡醫療上必要之注意，並應先取得接受試驗者之書面同意；受試驗者為無行為能力或限制行為能力人，應得其法定代理人之同意。
- 前項書面，醫療機構應記載下列事項，並於接受試驗者同意前先行告知：
 - 一、試驗目的及方法。二、可能產生之副作用及危險。三、預期試驗效果。四、其他可能之治療方式及說明。五、接受試驗者得隨時撤回同意。

放棄治療

■ 知情同意之濫觴

- 同意治療：治療同意書
- 不同意治療
- 放棄（拒絕）治療：放棄（拒絕）治療意願書

■ 不同意治療與放棄（拒絕）治療之分際

倫理面向：知情同意



- 知情同意原則：
 - 告知：合理及具體病人說
 - 能力：行為能力說？
 - 自願：無強暴脅迫
- 例外：
 - 緊急醫療
 - 強制醫療

拒絕治療

- 醫師認為病患**神智清楚**之理由
- 告知拒治療之**危險**為何
- 醫師知悉病患**已瞭解**危險之證據
- 拒治療之**原因**
- 簽署自動出院書時任何**不尋常**情形
- **見證人**簽名

案例：知情同意之刑法效力

- 年近70歲的老人盧x，母親94年間因病急診仍告不治，1年多來提出告訴外，並四處陳情。昨天中午他突然闖進當時盧母就醫的基隆市署立基隆醫院急診室，持刀往急診室主任李xx頭、臉猛刺，所幸當時正就醫的2名基隆港警局員警馬上和保全員一起將盧某制伏，李xx 被刺中多刀，急救後尚未脫離險境。
- 衛生署和台灣急診醫學會昨均譴責此種暴力行為，急診醫學會理事長陳維恭要求衛生和警政單位應對多次急診暴力事件提出妥善解決辦法，並呼籲衛生署進行急診醫學評鑑時，有關急診室空間設計，不僅注重病人安全，更要注重醫師安全。
- 盧x近百歲的母親孫xx 94年11月間因呼吸困難送到署立基隆醫院，由急診室主任李xx (41歲) 急救，延至95年4月因肺炎死亡。.....

強制罪

- 刑法第304條
 - 以強暴、脅迫使人行無義務之事或妨害人行使權利者，處三年以下有期徒刑、拘役或三百元以下罰金。
 - 前項之未遂犯罰之。
- 侵害自由法益之犯罪
- 對於「意思決定自由」與「意思形成自由」之侵害

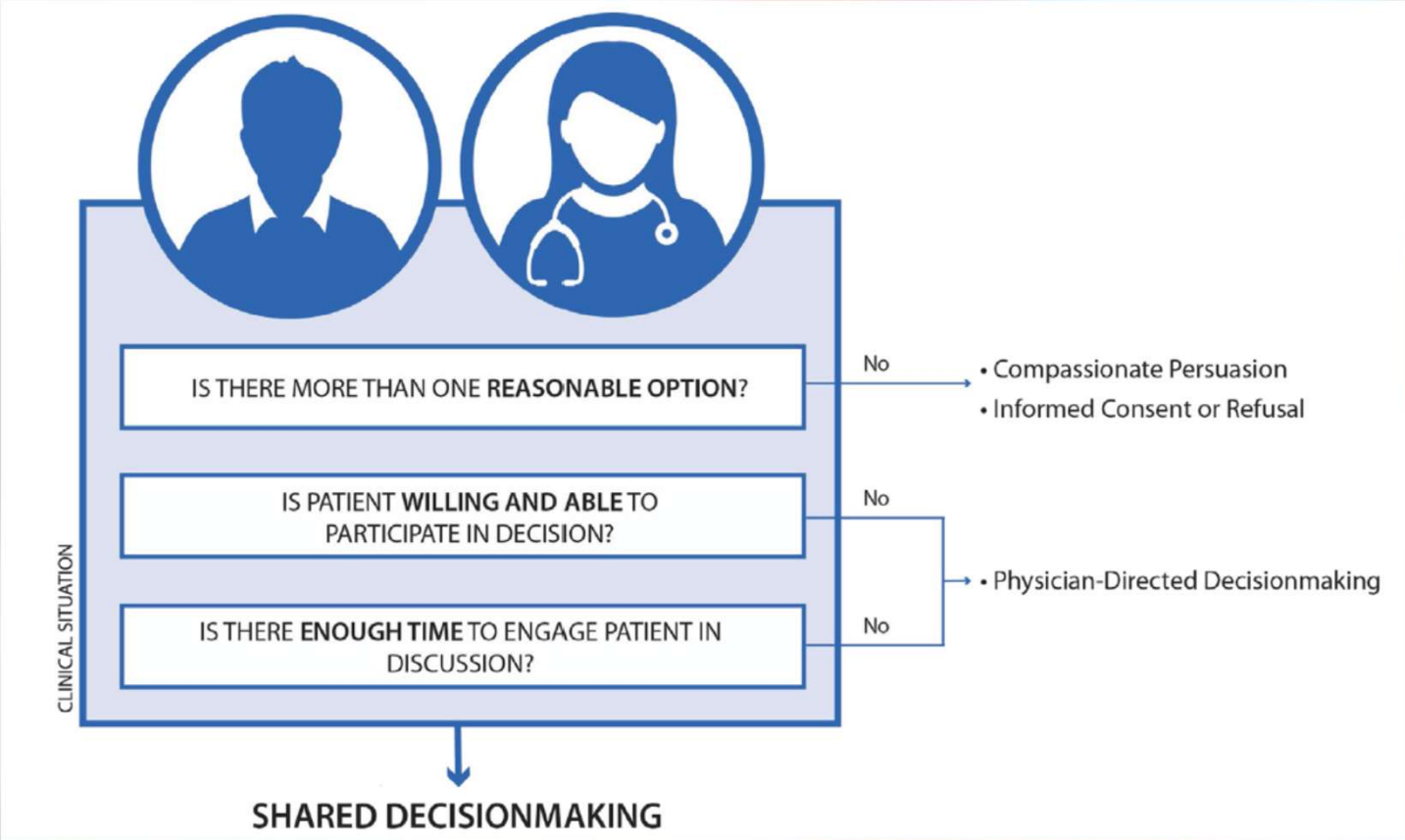
Shared Decision Agreements Transform Professional Liability Standards

by Jerry A. Green, JD

- *Shared decision making agreements shift the context for defining professional liability from **tort** to **contract**.*

侵權行為 → 契約

Shared Decision Making Model



[Ann Emerg Med. 2017;70:688-695.]

IS THIS CLINICAL SCENARIO APPROPRIATE FOR SHARED DECISIONMAKING?

- Factor 1: Clinical Uncertainty or Equipoise
- Factor 2: Patients' Decisionmaking
- Factor 3: Time

HAVING SHARED DECISIONMAKING CONVERSATION?

- Step 1: Acknowledge That a Clinical Decision Needs to Be Made
- Step 2: Share Information in Regard to Management Options and the Potential Harms, Benefits, and Outcomes of Each
- Step 3: Explore Patient Values, Preferences, and Circumstances
- Step 4: Decide Together on the Best Option for the Patient, Given His or Her Values, Preferences, and Circumstances

MISCONCEPTIONS ABOUT SHARED DECISION MAKING?

- Misconception 1: Shared Decisionmaking Is the Same as Informed Consent or Refusal
- Misconception 2: Shared Decisionmaking Is Simply Good Patient-Clinician Communication
- Misconception 3: The Goal of Shared Decisionmaking Is to Decrease Resource Use
- Misconception 4: Shared Decisionmaking Is a Means of Shifting Responsibility for Decisions to the Patient, Leaving the Patient to Make the Medical Decision Alone, Once Informed
- Misconception 5: Shared Decisionmaking Is Offering Patients Any Intervention They Would Like

[Ann Emerg Med. 2017;70:688-695.]

契約

- 民法總則第153-166-1條 (契約)
- 民法債總第245-1-270條 (債之效力: 契約)
- 民法債各第482-489條 (僱傭)
- 民法債各第490-514條 (承攬)
- 民法債各第528-552條 (委任)

當事人真意

■ 民法第98條:

- 解釋意思表示，應探求當事人之真意，不得拘泥於所用之辭句。

當事人真意

- 最高法院17 年上字第1118 號判例
 - 「解釋契約，固須探求當事人立約時之真意，不能拘泥於契約之文字，但契約文字業已表示當事人之真意，無須別事探求者，即不得反捨契約文字而更為曲解」...

知情同意 VS 醫病共享

	IC	SDM
Reason	Clinician protection	Meet needs of the patient
Intent	Confirm consent to proceed	Facilitate shared decision
Question	Okay to proceed?	What is the best for you/family?
Frame	"Reasonable" patients/clinicians	This specific patient
Information	Legal standard	Variable; dictated by patient preferences
Scope	Treatments and procedures	Most nonemergent decisions
Method	Disclosure to patient/family	Discussion <i>with</i> patient/family
Documentation	With or without signed form (sometimes required)	With or without decision aid

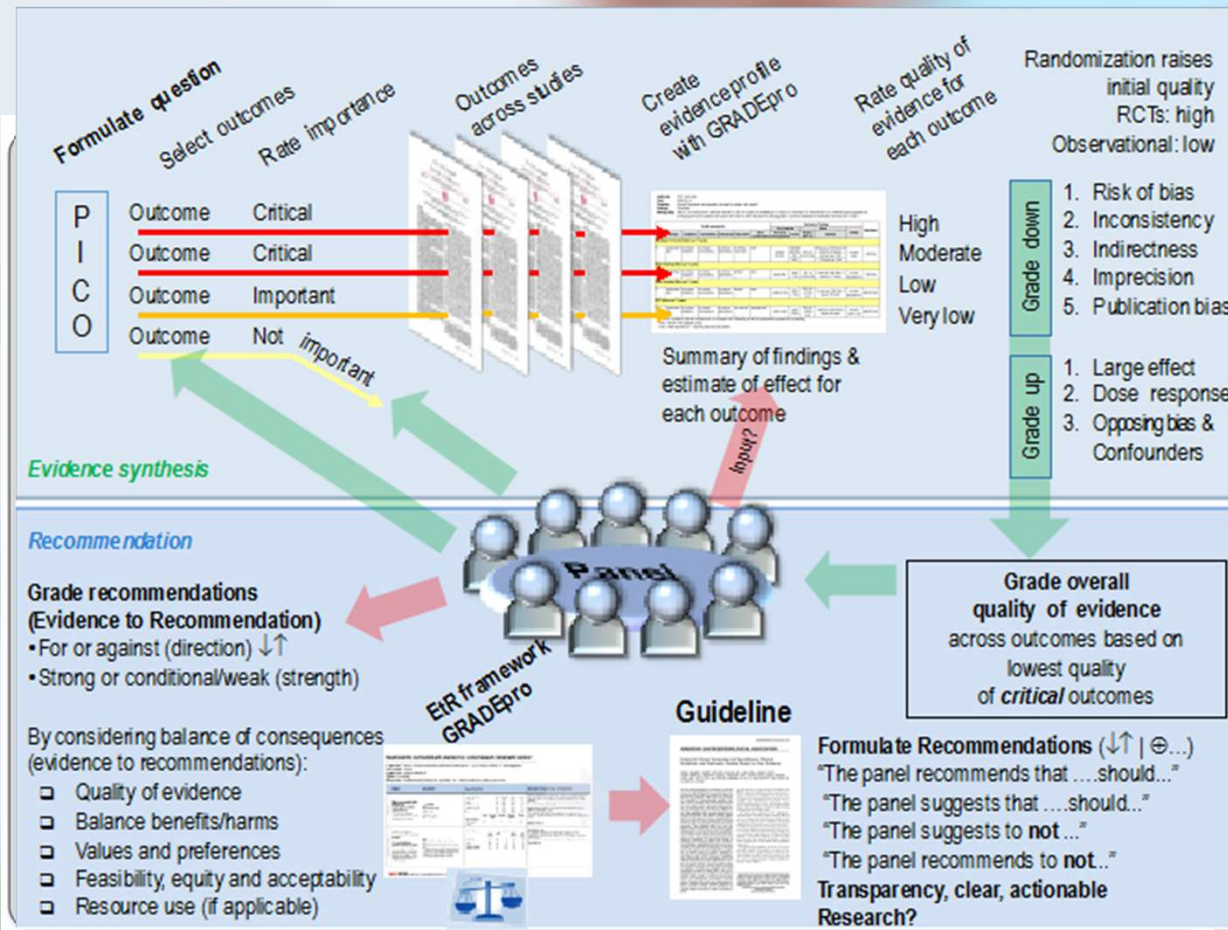
IC = informed consent; SDM = shared decision making.

醫病共享 對於法律 責任可能 的影響

Potential Effect of SDM	Clinician Behavior to Augment Protective Effects and Mitigate Liability Risks of SDM
Improved patient-provider relationship Reduction of invasive procedures	Focus on high-quality communication and patient-centered dialogue Deliver unbiased, high-quality information regarding alternative treatments or procedures, when appropriate
Documentation of detailed discussion	Document discussions well or use accurate decision aids and document their use within the medical record
Inappropriate patient selection	Identify features of patients or environment that may preclude appropriate use of SDM
Departure from standard of care	Understand local laws and employ SDM cautiously when it conflicts with usual care in states with "locality rule"

SDM = shared decision making.

GRADE



Determinants of the strength of recommendation

Factors that can strengthen a recommendation	Comment
Quality of the evidence	The higher the quality of evidence, the more likely is a strong recommendation.
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable consequences, the more likely a strong recommendation warranted. The smaller the net benefit and the lower certainty for that benefit, the more likely weak recommendation warranted.
Values and preferences	The greater the variability in values and preferences, or uncertainty in values and preferences, the more likely weak recommendation warranted.
Costs (resource allocation)	The higher the costs of an intervention – that is, the more resources consumed – the less likely is a strong recommendation warranted



具體病人說成為通說？

SDM為阻卻違法事由？

與病人自主權相關法律競合？

當
醫病共享決策
用之於
知情同意

法定阻卻違法事由

- 依法令之行為 (刑法第21條第1項)
- 公務員依所屬上級公務員職務上命令所為的行為 (刑法第21條第1項)
- 業務上正當行為 (刑法第22條)
- 正當防衛：對於現在不法之侵害，出於防衛自己或他人權利之行為。(刑法第23條)
- 緊急避難：避免自己或他人生命、身體、財產、自由之緊急危難而出於不得已之行為。(刑法第24條)

超法規阻卻違法事由

- 自助行為(民法第151條)
- 占有人之自力救濟(民法第960條)
- 現行犯之逮捕(刑事訴訟法第88條)
- 義務衝突
- 得被害人同意
- 醫病共享決策?

Can shared
decision-making
reduce medical
malpractice
litigation? A
systematic review



BMC Health Serv Res. 2015; 15: 167.

Two or more reasonable treatment or screening options are available

Informed discussion about the harms and benefits of available options and patient preferences considered

The doctor chooses a treatment or screening option without discussing harms and benefits with the patient

This may involve a decision support intervention

This may involve decision coaching*

This may involve clinicians' training in SDM skills

This may involve poor information & communication

This may involve ignoring patient views and concerns

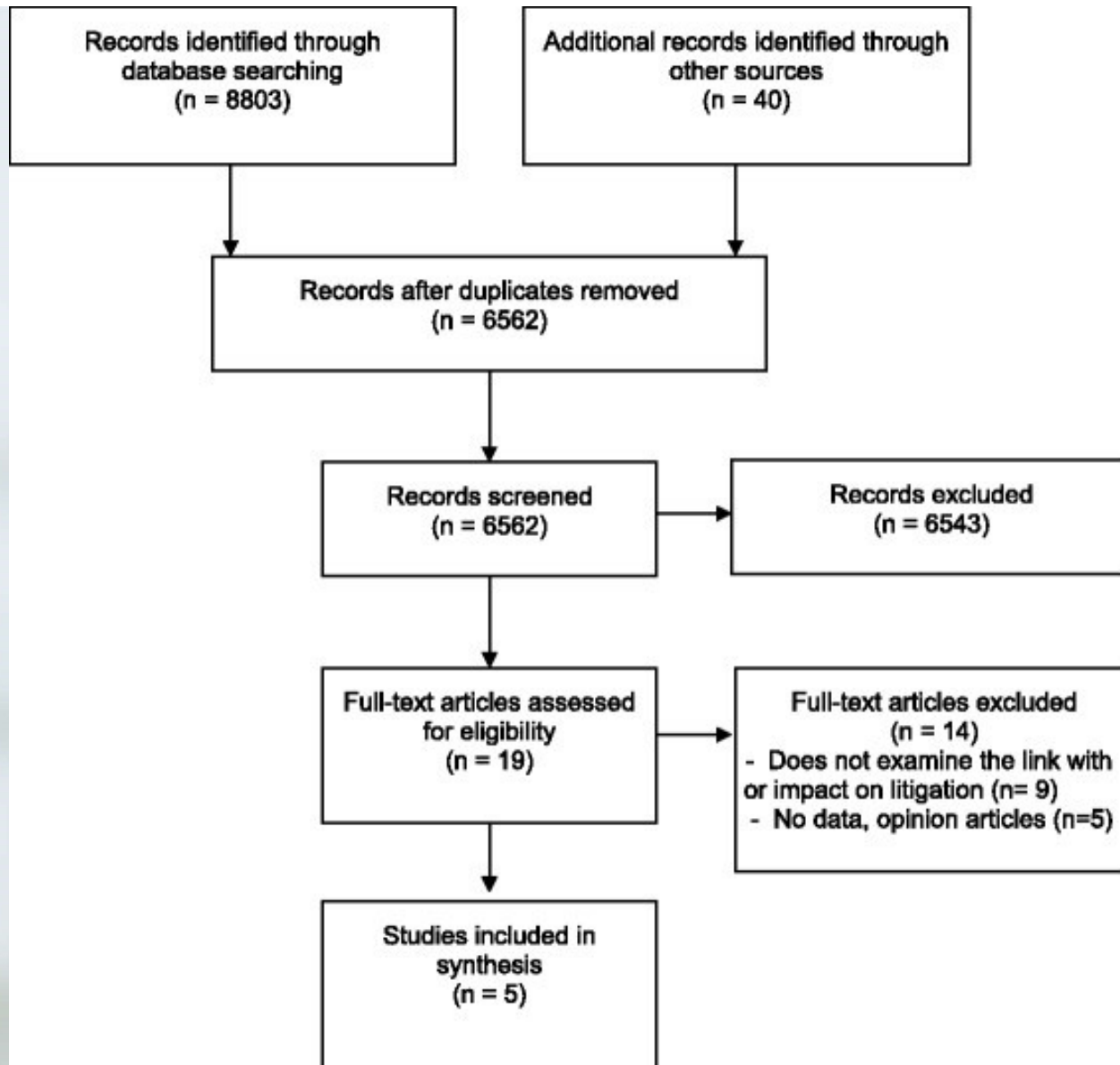
This may involve poor informed consent

Improved satisfaction and decision outcomes: more knowledge, less regret, anxiety and decisional conflict

Poor understanding, surprise, anger, grief, and/or regret if the outcome is negative or unexpected

Likely reduced medical malpractice litigation and associated costs

Increased risk of medical malpractice litigation and associated costs



Two or more reasonable treatment or screening options are available

Shared decision-making model
The health professional informs patients of known harms and benefits and diagnoses patients' preferences

'Defensive medicine' model
The health professional orders more tests and procedures without discussing harms and benefits with the patient.

The choice made **does not meet the standard of care** (e.g. optional screening test not ordered) and the patient experiences adverse outcomes

The choice made **meets the standard of care** (e.g. optional screening test ordered) and the patient experiences adverse outcomes

The choice made **meets the standard of care** (e.g. optional screening test ordered). The patient experiences adverse outcomes

The choice made **does not meet the standard of care** (e.g. optional screening test not ordered). The patient experiences adverse outcomes

Discussion not documented

Discussion documented in notes

Decision aid used

Discussion not documented

Discussion documented in notes

Decision aid used

The plaintiff's lawyer argues that the risks and benefits of the test should have been discussed with the patient

No medico-legal protection

Medium risk

Likely medico-legal protection
Low risk

Low to medium risk

Likely medico-legal protection
Low risk

Medico-legal protection
Low risk

Low to medium risk

No medico-legal protection

A photograph of a group of people in a meeting, looking down at something. A yellow text box is overlaid on the image, containing a title and a list of bullet points. The background is a blurred office setting.

小結

- 醫病共享決策 有助於探求 當事人真義
- 醫病共享決策 將 侵權行為 轉換為 契約問題
- 期待 醫病共享決策 有效減少 醫療訴訟
- 期待 醫病共享決策 能夠成為 超法規阻卻違法事由
- 疑慮: 醫病共享決策 是否令 知情同意 改採 具體病人說?



感謝聆聽