



Mahidol University  
Faculty of Medicine Siriraj Hospital

ศูนย์ความเป็นเลิศด้านการศึกษาวิทยาศาสตร์สุขภาพ  
คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล

# Teaching doctor-patient communication

การสื่อสารที่ดี มีวิธีอย่างไร

และสอนแพทย์อย่างไร ให้สื่อสารกับผู้ป่วยแล้วเกิดผลดีที่สุด

ระหว่างวันที่ 18-20 ตุลาคม 2560

ณ ห้องประชุมสมาคมศิษย์เก่าแพทย์ศิริราช ชั้น 2 คณะแพทยศาสตร์ศิริราชพยาบาล

## เอกสารประกอบการอบรม



ติดต่อสอบถาม

ศูนย์ความเป็นเลิศด้านการศึกษาวิทยาศาสตร์สุขภาพ (ศศว)  
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## Part I : Essential doctor-patient communication skills

**วันพุธที่ 18 ตุลาคม พ.ศ. 2560****วิทยากรหลัก****วิทยากรร่วม**

08.00 - 08.30 น. ลงทะเบียนภาคเช้า

08.30 - 10.00 น. Principles of communication

อ. นพ. ชรินทร์ ลิ้มวงศ์

รศ.ดร. นพ.เชิดศักดิ์ ไอรมณีรัตน์

10.00 - 10.15 น. พักรับประทานอาหารว่าง

10.15 - 12.00 น. Active listening

ผศ. พญ.ธัชวรรณ จิระติวานนท์

รศ.ดร. นพ.เชิดศักดิ์ ไอรมณีรัตน์

รศ. นพ.สุพจน์ พงศ์ประสพชัย

12.00 - 13.00 น. พักรับประทานอาหารกลางวัน

13.00 - 14.30 น. Informative counseling

รศ.ดร. นพ. สืบวงศ์ จุฑาภิสิตธิ

รศ.ดร. นพ.เชิดศักดิ์ ไอรมณีรัตน์

อ. นพ.ศิริส จิตประไพ

14.30 - 14.45 น. พักรับประทานอาหารว่าง

14.45 - 16.00 น. Breaking bad news

รศ. นพ.สุพจน์ พงศ์ประสพชัย

รศ. พญ. พรพรรณ กูมานะชัย

อ. นพ.ศิริส จิตประไพ

**วันพฤหัสบดีที่ 19 ตุลาคม พ.ศ. 2560**

08.00 - 08.30 น. ลงทะเบียนภาคเช้า

08.30 - 10.30 น. Disclosure of medical errors  
negligence, and complications

ผศ. นพ.ตรีภพ เลิศบรรณพงษ์

ผศ. พญ.ธัชวรรณ จิระติวานนท์

รศ.ดร. นพ. สืบวงศ์ จุฑาภิสิตธิ

ศ. แสง บุญเฉลิมวิภาส

รศ.ดร. นพ.เชิดศักดิ์ ไอรมณีรัตน์

อ. นพ.ศิริส จิตประไพ

ผศ. พญ.น้ำทิพย์ ไตรยสุนันท์

10.30 - 10.45 น. พักรับประทานอาหารว่าง

10.45 - 12.00 น. Advanced care planning

รศ. นพ.รุ่งนรินทร์ ประดิษฐ์สุวรรณ

รศ. นพ.สุพจน์ พงศ์ประสพชัย

รศ.ดร. นพ.เชิดศักดิ์ ไอรมณีรัตน์

ผศ. พญ.ธัชวรรณ จิระติวานนท์

12.00 - 13.00 น. พักรับประทานอาหารกลางวัน

13.00 - 14.30 น. End-of-life discussion

รศ. นพ.สุพจน์ พงศ์ประสพชัย

ผศ. พญ.บุญทริกา สุวรรณวิบูลย์

อ. นพ.ศิริส จิตประไพ

14.30 - 14.45 น. พักรับประทานอาหารว่าง

14.45 - 16.00 น. communication with relatives  
with bereavement

อ. นพ. ปเนต ผู้กฤตยาคามี

รศ.ดร. นพ.เชิดศักดิ์ ไอรมณีรัตน์

รศ. นพ.สุพจน์ พงศ์ประสพชัย

16.00 - 16.30 น. Summary

รศ.ดร. นพ.เชิดศักดิ์ ไอรมณีรัตน์

## Part II: How to teach communication skills

วันศุกร์ที่ 20 ตุลาคม พ.ศ. 2560

วิทยากรหลัก

วิทยากรร่วม

08.00 - 08.30 น. ลงทะเบียนภาคเช้า

08.30 - 09.45 น. Basic principles of communication skills teaching

รศ.ดร. นพ.เชิดศักดิ์ ไอรอมณีรัตน์

ผศ. พญ.กษณา รักษาภรณ์

09.45 - 10.00 น. พักรับประทานอาหารว่าง

10.00 - 11.00 น. Facilitation techniques

ผศ. พญ.กษณา รักษาภรณ์

รศ.ดร. นพ.เชิดศักดิ์ ไอรอมณีรัตน์  
รศ. นพ.สุพจน์ พงศ์ประสพชัย

11.00 - 12.00 น. How to assess communication Skills

รศ.ดร. นพ.เชิดศักดิ์ ไอรอมณีรัตน์

รศ.ดร. นพ. สืบวงศ์ จุฑาภิสิทธิ์

12.00 - 13.00 น. พักรับประทานอาหารกลางวัน

13.00 - 14.00 น. Group activity: Designing a lesson

รศ.ดร. นพ.เชิดศักดิ์ ไอรอมณีรัตน์

อ. นพ.ศิริส จิตประไพ

14.00 - 14.45 น. Presentation of communication lessons I

รศ.ดร. นพ.เชิดศักดิ์ ไอรอมณีรัตน์

รศ. นพ.สุพจน์ พงศ์ประสพชัย

14.45 - 15.00 น. พักรับประทานอาหารว่าง

15.00 - 15.45 น. Presentation of communication lessons II

รศ.ดร. นพ. สืบวงศ์ จุฑาภิสิทธิ์

อ. นพ.ศิริส จิตประไพ

15.45 - 16.00 น. Summary

รศ.ดร. นพ.เชิดศักดิ์ ไอรอมณีรัตน์

หมายเหตุ กำหนดการอาจมีการเปลี่ยนแปลงตามความเหมาะสม

## รายชื่อผู้ร่วมอบรม

## Part I : Essential doctor-patient communication skills 18-19 Oct 2017

กลุ่มที่ 1					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	พญ.	ชนันยา	ทอเกียรติ	โรงพยาบาลพรัตนราชธานี	สาขา ศัลยศาสตร์
2	อ. นพ.	สุธิตินิต	หัตถพรสวรรค์	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาศัลยศาสตร์
3	รศ. นพ.	รวีศ	เรืองตระกูล	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาศัลยศาสตร์
4	พญ.	วสี	ธีราทร	โรงพยาบาลพุทธชินราช	แผนกวิสัญญีวิทยา
5	พญ.	อุบลวรรณ	เชียรโพธิ์ภักษ์	โรงพยาบาลพระนั่งเกล้า	วิสัญญีวิทยา
6	พญ.	สิริรัตน์	ลิมกุล	โรงพยาบาลพระนั่งเกล้า	งานวิสัญญีวิทยา
กลุ่มที่ 2					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	พญ.	กมลทิพย์	เลิศชัยสภาพร	โรงพยาบาลจุฬารัตน์	งานอายุรกรรม
2	อ. พญ.	ฉัตรี	หาญทวีพันธุ์	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาอายุรศาสตร์
3	นพ.	สุทัศน์	ภัทรวรรณธรรม	โรงพยาบาลกลาง	เวชศาสตร์ฟื้นฟู
4	ผศ. พญ.	จันทิมา	รองวิริยะพานิช	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชารังสีวิทยา
5	นพ.	สุสันต์	กนกศิลป์	สำนักวิชาแพทยศาสตร์ มหาวิทยาลัยเทคโนโลยีสุรนารี	ศัลยศาสตร์ทั่วไป
6	พญ.	ธนาทิพย์	ตันติวัฒน์	คณะแพทยศาสตร์วชิรพยาบาล	สาขารังสี
7	นางสาว	เปรมสุดา	แจ่มจันทร์	คณะแพทยศาสตร์ศิริราชพยาบาล	สถานการแพทย์แผนไทยประยุกต์
กลุ่มที่ 3					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	พญ.	เพ็ญพิมล	ยิ่งยง	โรงพยาบาลเมตตาประชารักษ์ (วัดไร่ขิง)	จักษุวิทยา
2	รศ. พญ.	อติพร	ดวงทอง	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาจักษุวิทยา
3	อ. พญ.	เพ็ญพร	ศักดิ์ศิริวุฒไธ	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาจักษุวิทยา
4	รศ. นพ.	ปารยะ	อาศนะเสน	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาโสต นาสิก ลาริงซ์วิทยา
5	รศ. พญ.	รสสุคนธ์	ศขรัตน์	คณะแพทยศาสตร์ มหาวิทยาลัยนครสวรรค์	ภาควิชาจักษุวิทยา
6	ผศ. ทพ.ดร.	เกศกาญจน์	เกษวายุธ	คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย	ภาควิชาชีวเคมี
กลุ่มที่ 4					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	ผศ. พญ.	นิตา	พุกษะรัตนานท์	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
2	พญ.	สิริกาญจน์	ทองใหม่	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
3	ผศ. พญ.	พจนีย์	ผดุงเกียรติวัฒนา	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
4	ผศ. นพ.	ยุทธพงศ์	พุทธรักษา	คณะแพทยศาสตร์ มหาวิทยาลัยนครสวรรค์	ภาควิชากุมารเวชศาสตร์
5	อ. พญ.	ภัทรจิต	ภัทโรดม	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาเวชศาสตร์ป้องกันและสังคม
6	รศ. พญ.	สายฝน	ชวาลไพบลีย์	คณะแพทยศาสตร์ศิริราชพยาบาล	สูติศาสตร์-นรีเวชวิทยา
กลุ่มที่ 5					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	ดร.	มนต์รัตน์	จุลเนตร	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาปรสิตวิทยา
2	รศ. นพ.	ชัยเจริญ	ตันธเนศ	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาพยาธิวิทยาคลินิก
3	พญ.	สาธิตา	วิรัชชกุล	โรงพยาบาลพุทธโสธร	ภาควิชาจิตเวชศาสตร์
4	พญ.	วินิตรา	แก้วพิลา	คณะแพทยศาสตร์ โรงพยาบาลรามธิบดี มหาวิทยาลัยมหิดล	จิตเวชศาสตร์
5	พญ.	ทานตะวัน	อวิรุทธ์วรกุล	คณะแพทยศาสตร์ โรงพยาบาลรามธิบดี มหาวิทยาลัยมหิดล	จิตเวชศาสตร์
6	นพ.	อำนาจ	รักษงาน	ศูนย์แพทยศาสตรศึกษาชั้นคลินิก โรงพยาบาลเจ้าพระยาอภัยภูเบศร	สาขาเวชศาสตร์ครอบครัว
7	อาจารย์	ศุภกิจ	สุวรรณไตรย์	คณะแพทยศาสตร์ศิริราชพยาบาล	สถานการแพทย์แผนไทยประยุกต์
กลุ่มที่ 6					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	อ. นพ.	สุรเชษฐ์	วงศ์วิทยาพาณิชย์	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชานิติเวชศาสตร์
2	นพ.	ไพสิฐ	นาตประเสริฐ	โรงพยาบาลสระบุรี	ฝ่ายเวชศาสตร์ฉุกเฉินและนิติเวช
3	นพ.	สถิตย์	นิรมิตรมหาปัญญา	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาอายุรศาสตร์
4	พญ.	แพรว	สุวรรณศรีสุข	คณะแพทยศาสตร์ มหาวิทยาลัยนครสวรรค์	ภาควิชาอายุรศาสตร์
5	พญ.	ขวัญฤทัย	ศรีพาทกุล	โรงพยาบาลมหาราช นครราชสีมา	อายุรศาสตร์
6	พญ.	ชลิตา	ชุมยวง	คณะแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์	หน่วยนิติเวชศาสตร์และพิษวิทยา ภาควิชาพยาธิวิทยา
7	อาจารย์	พนิตสุภา	เชื้อขัง	คณะแพทยศาสตร์ศิริราชพยาบาล	สถานการแพทย์แผนไทยประยุกต์



## รายชื่อผู้ร่วมอบรม

## Part II: How to teach communication skills 20 Oct 2017

กลุ่มที่ 1					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	พญ.	ชนันยา	ห่อเกียรติ	โรงพยาบาลพรตนาชธานี	สาขา ศัลยศาสตร์
2	อ. นพ.	สุริคณิต	หัตถพรสวรรค์	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาศัลยศาสตร์
3	ผศ. นพ.	บัลลังก์	ม้วยเผือก	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ศัลยศาสตร์ทั่วไป
4	นพ.	ทรงพล	พุทธศิริ	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
5	พญ.	ศิริพร	ฐิติสกุลวงษ์	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	สาขา สูติศาสตร์และนรีเวชวิทยา
6	นาวาโท นพ.	ประพนธ์	จารุยาวงศ์	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	สาขา สูติศาสตร์และนรีเวชวิทยา
กลุ่มที่ 2					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	ผศ. พญ.	นิสา	พฤกษ์รัตนานท์	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
2	พญ.	สิริกาญจน์	ทองใหม่	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
3	นพ.	สมชาย	ศิริเจริญไทย	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
4	ผศ. พญ.	พจนีย์	ผดุงเกียรติวัฒนา	วิทยาลัยแพทยศาสตร์ มหาวิทยาลัยรังสิต	ภาควิชาสูติศาสตร์-นรีเวชวิทยา
5	รศ. พญ.	กลีบสไบ	สรรพกิจ	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชากุมารเวชศาสตร์
6	ผศ. นพ.	ยุทธพงศ์	พุทธรักษา	คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น	ภาควิชากุมารเวชศาสตร์
กลุ่มที่ 3					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	พญ.	กมลทิพย์	เลิศชัยสถาพร	โรงพยาบาลจุฬารัตน์	งานอายุรกรรม
2	อ. พญ.	ฉัตรี	หาญทวีพันธุ์	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาอายุรศาสตร์
3	ผศ. นพ.	พรพจน์	เปรมโยธิน	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาอายุรศาสตร์
4	พญ.	แพรว	สุวรรณศรีสุข	คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น	ภาควิชาอายุรศาสตร์
5	นพ.	สุขสันต์	กนกศิลป์	สำนักวิชาแพทยศาสตร์ มหาวิทยาลัยเทคโนโลยีสุรนารี	ศัลยศาสตร์ทั่วไป
6	พญ.	ขวัญฤทัย	ศรีพวงทูล	โรงพยาบาลมหาสาร นครราชสีมา	อายุรศาสตร์
กลุ่มที่ 4					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	ผศ. พญ.	จันทิมา	รองวิริยะพานิช	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชารังสีวิทยา
2	รศ. พญ.	ปรียชาติ	ปาจารย์	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชารังสีวิทยา
3	ศ. พญ.	อรสา	ชวาลภาฤทธิ์	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชารังสีวิทยา
4	พญ.	วสี	ธีราทร	โรงพยาบาลพุทธชินราช	แผนกวิสัญญีวิทยา
5	พญ.	อุบลวรรณ	เฮียรโพธิ์กริช	โรงพยาบาลพระนั่งเกล้า	วิสัญญีวิทยา
6	พญ.	สิริรัตน์	ลิ้มกุล	โรงพยาบาลพระนั่งเกล้า	งานวิสัญญีวิทยา
กลุ่มที่ 5					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	รศ. พญ.	อดิพร	ดวงทอง	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาจักษุวิทยา
2	อ. พญ.	เพ็ญพร	ศักดิ์ศิริวิฑูโร	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาจักษุวิทยา
3	ผศ. นพ.	จักรพงษ์	นะมาตร	คณะแพทยศาสตร์ศิริราชพยาบาล	ภาควิชาจักษุวิทยา
4	พญ.	เพ็ญทิมล	ยิ่งยง	โรงพยาบาลเมตตาประชารักษ์ (วัดไร่ขิง)	จักษุวิทยา
5	รศ. พญ.	รสสุคนธ์	คชรัตน์	คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น	ภาควิชาจักษุวิทยา
6	ผศ. พญ.ดร.	เกศกาญจน์	เกศวุธ	คณะทันตแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย	ภาควิชาชีวเคมี
กลุ่มที่ 6					
ลำดับ	คำนำหน้า	ชื่อ	สกุล	สังกัด	หน่วยงาน/ภาควิชา
1	นพ.	ไพสิฐ	นาตประเสริฐ	โรงพยาบาลสระบุรี	ฝ่ายเวชศาสตร์ฉุกเฉินและนิติเวช
2	พญ.	สาธิตา	วีรัชกุล	โรงพยาบาลพุทธโสธร	ภาควิชาจิตเวชศาสตร์
3	พญ.	วินิทรา	แก้วพิลา	คณะแพทยศาสตร์ โรงพยาบาลรามธิบดี มหาวิทยาลัยมหิดล	จิตเวชศาสตร์
4	พญ.	ทานตะวัน	อวีรุทธ์วรกุล	คณะแพทยศาสตร์ โรงพยาบาลรามธิบดี มหาวิทยาลัยมหิดล	จิตเวชศาสตร์
5	นพ.	สุทัศน์	ภัทรวรรณ	โรงพยาบาลกลาง	เวชศาสตร์ฟื้นฟู



## เอกสารประกอบการอบรม



18 Oct 2017





18 Oct 2017

หัวข้อ : Principles of communication

## Principles of Communication

**นพ. ชรินทร์ ลิ้มวงศ์**  
ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์ศิริราชพยาบาล

### Common problems in counseling

- "Listening but do not hear"
- Bad news are always difficult
- Enough time should be given but counselor's time is of the essence
- A problem of too many people
- How much is sufficient information ?
- To know when not to answer
- How to avoid informative counseling without support ?
- How to learn to direct the situation ?

### Fact about communication time

- Writing
- Reading
- Listening
- Talking
- Acting

**An Effective Communications Model**

```

graph LR
    S[SENDER] -- "1. Sends message" --> R[RECEIVER]
    R -- "2. Hears and responds" --> S
    S -- "3. Clarifies" --> R
    R -- "4. Confirms" --> S
    
```

### Communication vs. Counseling

- Common Goal : Problem solving
- Clear role : counselor vs counselee
- Certain different rules
  - Frequently non-directive
  - Non-judgemental
  - Providing empathy and support

### Different Types of Counseling

- Directive counseling
- Advocacy counseling
- Informative counseling
- Supportive counseling

Riccardi VM, Kurtz SM. Communication and counseling in health care. Springfield, Illinois 1983.

### Components of an effective counseling

- Counselor
- Counselee
- Content
- Circumstance

## A. Counselor

- I. Attitude
- II. Skills
- III. Manner / charisma

## Counselor (1) -Attitude

- Attitude
  - Faith
  - Empathy
  - Optimism
  - Realistic understanding
  - Unbiased view

## Counselor (2) - Skills

- Verbal communication skills
- Non-verbal communication skills

## Verbal skills

- Questioning
- Probing
- Repeating (Reiterating)
- Paraphrasing
- Reflection (Interpreting)
- Reframing
- Summarizing
- Encouraging

## Non-Verbal skills

- Vocal quality
- Speed of voice
- Volume of voice
- Listening
- Silencing
- Touching
- Refraining
- Interrupting
- Observing
- Facial expression

## Listening Bad Habits

- ขาดความอดทน
- พูดแทรกขณะฟัง
- รีบด่วนสรุป คิดล้นใจ โดยฟังไม่ครบถ้วน
- ให้คำแนะนำเหมือนเป็นผู้ ถูกหลอน
- จดบันทึกอย่างตั้งใจ แต่ไม่แสดงว่าตั้งใจฟัง
- ฟังแล้ว ไม่มี การแสดงออกตอบสนอง
- อารมณ์เสีย เมื่อข้อมูลไม่ตรงใจ ไม่พอใจ
- เปลี่ยนเรื่องไปมาขณะสนทนา

### Counselor (3) - Manner/Charisma

- Maturity
- Politeness
- Courtesy
- Sensitivity
- Respect

### B. Content (1)

- Medical
  - information
  - diagnosis, burden
  - prognosis
  - options
- Psychological
  - normal coping mechanism
  - help / service

### B. Content (2)

- Contents vary depending upon the types of counseling for each session / moment
- Consider how much to give and how many times “give small bites if you can”
- Frequently what you plan to do is not what is eventually done !

### How to Inform ?

- Verbal skills
  - พูดภาษาเดียวกัน
  - พูดหรือบอกความจริงที่จำเป็น อาจจะไม่ทั้งหมด
  - พูดให้เข้าใจง่าย
  - พูดหรือบอกทีละน้อย ในเรื่องที่ยาก
  - พูดให้สบายใจ สบายใจขึ้น สบายใจที่สุดที่จะเป็นไปได้
  - พูดจากเรื่องใกล้ตัว ไปสู่ไกลตัว
  - พูดสารที่มีความหมายเชิงบวกนำลบ

### B. Content (3)

- Keep in mind of the following

Always tell the truth  
 Use language patient understands  
 Prioritize what you will say  
 Use wording that minimizes reaction  
 but convey similar meaning  
 Give time period in range

### B. Content (4)

- Keep in mind of the following

Make use of inference not  
 personalized opinion  
 Avoid blaming  
 Assess understanding periodically  
 Allow questions at appropriate times

### C. Counselor

- Difficult patients
- Family counseling
- Barriers to understanding
- Unexpected circumstances
- Terminally-ill and end-of-life situations

### When is it appropriate to counsel ?

- Patient's right to know
- Patient's desire to know
- Patient's need to know
- Patient's readiness to know

	Right	Need	Desire	Ready
Counsel now	Y	Y	Y	Y
Counsel later or withhold	Y	N	Y	N
Counsel anyway or withhold	Y	Y	N	Y/N
Withhold	N	Y/N	Y/N	Y/N
Withhold	Y	N	N	Y/N

### Withholding bad news

- Pt with unstable psychiatric condition
- Pt with active suicidal idea
- Pt with no family support
- Pt with imminent death
- Pt with comprehension difficulties : dementia, delirium, under influence of drugs/chemicals
- None of these is, by no means, an absolute contraindication

### D. Circumstance (1)

- Place
  - privacy and quietness
  - avoid bedside for advocacy / supportive counseling
  - sitting down always
  - avoid confrontation
  - be prepared for emotional session
  - avoid interruption

### D. Circumstance (2)

- Opening
  - greeting
  - introduction
  - set agreement/rules
  - refer to pt by name
  - small talk first
  - assess what he/she knows
  - assess what he/she wants
  - goal setting

### D. Circumstance (3)

- Middle part (body)
  - two-way communication
  - use skills to convey contents
  - interrupt as minimal as possible
  - redirection if needed
  - responding to concerns / feeling

### D. Circumstance (4)

- Closing
  - Summarizing
  - Emphasizing what need to be decided and when (if apply)
  - Allow questioning
  - Assess feeling
  - Show appreciation
  - Make follow up plan



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หัวข้อ : Active listening

## ทักษะการฟังในการสื่อสารทางการแพทย์ (Listening Skill in Medical Communication)

ผศ.พญ. ถัษฐรณ จิระติวานนท์

ทักษะการฟังเป็นทักษะที่สำคัญ และเป็นทักษะพื้นฐานสำหรับการสื่อสาร หากแต่เป็นทักษะที่มีถูกละเลย ไม่ได้รับความสำคัญ และขาดการฝึกฝน ในบทบาทของแพทย์ที่ดูแลผู้ป่วย จำเป็นอย่างยิ่งที่ต้องทำความเข้าใจกับทักษะนี้ เพื่อการดูแลผู้ป่วยที่มีประสิทธิภาพต่อไป

ทักษะการฟังเป็นทักษะที่มนุษย์ใช้มากที่สุดเมื่อเทียบกับการสื่อสารอื่นในชีวิตประจำวัน คือ ประมาณ 45% ในขณะที่การพูดใช้เวลาไป 30%, การอ่าน 16% และเขียน 9%(1) แต่เป็นเรื่องน่าเสียดายที่มีผู้ที่เข้าใจการเป็นผู้ฟังที่ดีไม่มากนัก แม้การฟังนั้นจะเป็นเพียงการฟังเพื่อให้ได้ข้อมูล (informational listening) แต่ข้อมูลที่ผู้พูดส่งไปมักถูกละเลย เข้าใจผิด และถูกตีความอย่างรวดเร็ว

ในภาษาอังกฤษ คำว่าฟัง ตรงกับคำว่า listen ซึ่งต่างจากคำว่าได้ยิน ซึ่งตรงกับคำว่า hear การฟังเป็นทักษะที่ลึกซึ้งกว่าการได้ยินมากนัก เพราะเป็นกระบวนการที่ซับซ้อนที่ต้องอาศัยการตีความและความเข้าใจในเนื้อความที่ได้รับ ในขณะที่การได้ยิน เป็นเพียงการรับรู้ทางประสาทสัมผัสการได้ยิน (auditory sensation) ไปยังสมองเท่านั้น เราอาจจะสามารถโต้ตอบหรือพูดตามคำพูดของผู้พูดได้ แต่หากเราไม่ได้เข้าใจเรื่องที่ถูกพูดกำลังพูด ก็ไม่ใช่การฟังที่แท้จริง

ในการสื่อสารกับผู้ป่วย การฟังเป็นทักษะพื้นฐานของการดูแลผู้ป่วยโดยมีผู้ป่วยเป็นศูนย์กลาง (patient centered model) เราใช้การฟังเพื่อให้ได้ข้อมูลเพื่อการวินิจฉัย เพื่อการตัดสินใจเลือกการรักษา เพื่อการเข้าใจผู้ป่วยแบบเป็นองค์รวม และที่สำคัญ เพื่อการสร้างความสัมพันธ์ระหว่างแพทย์และผู้ป่วย (doctor-patient relationship) การไม่รับฟังของแพทย์เป็นเหตุผลหลัก ที่ทำให้ผู้ป่วยเกิดความไม่พึงพอใจในทางการแพทย์ และส่งผลต่อการรักษาผู้ป่วยได้

### การฟังอย่างตั้งใจ (active listening)

การฟังอย่างตั้งใจ เป็นทักษะเฉพาะในการสื่อสาร เป็นการฟังเพื่อการเข้าใจความหมายที่แท้จริงของการสื่อสารนั้น ทั้งความหมายของคำ และความรู้สึกของผู้พูด โดยมีทักษะย่อยที่เกี่ยวข้อง ดังนี้ (2, 3)

#### 1. ทักษะที่บ่งว่าตั้งใจฟัง (Attending skill)

การฟังที่ดี นอกจากเราจะต้องตั้งใจ และพยายามเข้าใจความหมายของการสนทนานั้นแล้ว การแสดงออกว่าเราเป็นผู้ฟังที่ดีมีความสำคัญเช่นกัน ส่งผลให้ผู้พูดรู้สึกไว้วางใจ รู้สึกถึงการให้เกียรติ และพร้อมที่จะสนทนาต่อ โดยการสนทนาควรอยู่ในสถานที่ที่ไม่ถูกรบกวน มีการวางท่าทางขณะสนทนาให้เหมาะสม ไม่แสดงออกถึงการไม่ใส่ใจ ระวังระวังภาษากายที่ทำให้ดูน่ารำคาญ เช่น นั่งเข่าขา คางปากก้า เขามือเกาะโต๊ะ และที่สำคัญ ต้องฝึกการสบตาที่สื่อความหมาย (eye contact) การสบตา ไม่จำเป็นต้องมองตาตลอดเวลา หากผู้ฟังเข้าใจเรื่องราวที่ผู้พูดได้พูด รวมถึงมีความปรารถนาดีให้ สายตาที่มองออกไป จะเป็นสิ่งที่บ่งบอกได้เป็นอย่างดี

#### 2. ทักษะการติดตามการฟัง (Following skill)



ทักษะนี้ เป็นทักษะที่ช่วยให้ผู้พูดสามารถพูดต่อไป ด้วยความสบายใจ ในทิศทางที่เหมาะสม โดยเริ่มจากการสังเกตภาษากายของผู้พูด ว่ามีเรื่องราวที่อยากจะบอกหรือมีอะไรในใจ และเริ่มต้นการสนทนา โดยอาจเริ่มจากการสอบถามจากภาษากายที่เราสังเกตได้ เช่น “วันนี้ดูเครียดนะ มีอะไรอยากจะเล่าให้ฟังหรือไม่” และให้เวลากับผู้พูดสักครู่ เพื่อให้เขาได้ตัดสินใจว่าอยากจะเล่าให้ฟังหรือเปล่า และฟังต่ออย่างตั้งใจ

ในขณะที่ฟังนั้น เราสามารถทำให้ผู้ฟังเล่าต่อเนื่อง โดยการพูดประโยคสั้นๆ ที่แสดงให้เห็นว่าเราฟังอยู่ และเข้าใจสิ่งที่พูด เช่น อืม จริงเหรอ เล่าต่อซิ แล้วยังงัยต่อ โดยร่วมกับการถามคำถามที่มุ่งเน้นไปที่สิ่งที่ผู้พูดกำลังให้ความสำคัญ ถามแต่พอดี การถามที่เยอะเกินไป อาจทำให้ผู้พูดรู้สึกเหมือนถูกควบคุมการสนทนา หรือจ้องจับผิดผู้พูด

สิ่งที่ขาดไม่ได้ในทักษะนี้คือ การเงียบ (attentive silence) ผู้ฟังส่วนใหญ่มีแนวโน้มที่จะพูดมากกว่าการเงียบฟัง แม้ในขณะที่สนทนา ถ้ามีความเงียบเกิดขึ้น ผู้ฟังหลายคนจะรู้สึกอึดอัด เราเงียบเพื่อแสดงว่าเราตั้งใจ คิดตามสิ่งที่พูด และอยากให้ผู้พูดได้พูดต่อ การเงียบนั้นหากทำไปอย่างมีวัตถุประสงค์ จะช่วยให้ความรู้สึกอึดอัดนั้นลดลงได้

### 3. ทักษะการสะท้อนความรู้สึกรู้สึก (Reflecting skill)

หลักการสำหรับทักษะนี้ คือ เราจะสะท้อนความรู้สึกรู้สึกโดยไม่ตัดสินผู้พูด ในถ้อยคำที่กระชับ และถูกต้องกับความรู้สึกนั้นจริงๆ โดยมีทักษะที่ควรรู้จัก ดังนี้

1. Paraphrasing เป็นการตอบสนองสั้นๆ เกี่ยวกับข้อความที่ผู้พูดได้ ด้วยคำพูดของเราเอง
2. การสะท้อนอารมณ์ และความหมาย (reflecting feelings and meaning) โดยการจับความรู้สึกของผู้พูดในขณะนั้น รวมถึงการจับประเด็นที่ได้ แล้วสะท้อนออกมา เช่น “คุณ... รู้สึกเบื่อหน่ายกับการรักษา เพราะ ที่ผ่านมามีวิธีไหนทำให้หายขาดได้ ไช้ไหมคะ”
3. การสรุปประเด็น (summary) การสรุปประเด็นมีความสำคัญ โดยเฉพาะในกรณีที่มีการสนทนานั้นผู้ฟังมีความสับสนในอะไรบางอย่าง หรือมีปัญหาที่ต้องการการแก้ไข ช่วยในการประมวลผลความคิด ก่อนจะจบการสนทนา หรือเริ่มหัวข้อใหม่ โดยผู้ฟังจะต้องรวบรวมสิ่งที่ได้ฟังมา เลือกเฉพาะส่วนที่สำคัญ แล้วสรุปจุดหลักๆ ที่ทำให้ผู้พูดเข้าใจตัวเองได้ดีขึ้น

จะเห็นได้ว่า การฟัง ไม่ได้มีเฉพาะการได้ยินข้อมูลต่างๆ เท่านั้น การฟังที่ดี ต้องมีลักษณะของ “active listening” ซึ่งมีองค์ประกอบของ attending, following และ reflecting skill ที่ควรได้รับการฝึกฝนและพัฒนาอย่างต่อเนื่อง

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## Informed consent: Is it always necessary?

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### KEYWORDS

Informed consent;  
 Medical necessity

**Summary** Informed consent plays a pivotal role in human clinical research. It serves as a marker for the subject's comprehension of all the pertinent elements of the study. It is also a pledge by the investigator that during the trial, the rights and safety of the subject will be protected. Informed consent attempts to ensure that ethical behaviour will be upheld throughout the study. However, obtaining informed consent from certain vulnerable populations is a challenge, and thus warrants improvement. While informed consent is mandated for almost all clinical trial involving human subjects, there are situations of emergency research and trials with minimal risk that call for a waiver of the consent.

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### Introduction

Currently there are over 27,000 clinical studies underway in the United States.<sup>11</sup> While the noble goal of all these investigations is to further scientific knowledge for the betterment of our society, the safety of the human subjects involved in these studies and means of garnering this knowledge can not be overlooked.

When a clinical research project is being developed, it is necessary to assess the ethical aspects surrounding it and its impact on the subjects. However, informed consent is not the only ethical criteria to take into account; it also constitutes the

legal and ethical cornerstone for all research involving human subjects. Informed consent serves as a valuable tool in asserting proper regulations in clinical trials, as well as providing assurance of safety for the patient.

While most clinical studies can only be performed under an informed consent, there are exceptions to this rule. In situations such as emergency research or research with minimal risk to the subject, informed consent is not absolutely necessary. Nevertheless, efforts to protect the subject's rights and safety should be a principal concern in every clinical study.

### Definition of informed consent

Informed consent is the process of obtaining the permission of a subject to participation in studies and have an opportunity to decide about his or her healthcare. This notion originates from the legal

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and ethical right of the patient/subject to retain autonomy and from the ethical duty of the physician/researcher to involve the patient in health-care decisions. Informed consent also implies that a dialog has taken place about the nature of the decision, reasonable alternatives, relevant risks, benefits and uncertainties of the decision, and the comprehension and acceptance of the health-care decision by the patient/subject.<sup>10,4</sup>

### Historical context of informed consent

We need not look any further than recent history to highlight the importance of informed consent. There have been some paramount circumstances which have necessitated greater regulation of human subject medical research. The inception of informed consent has its roots in the Nuremberg Code of 1945. This code was formulated in response to the shocking discoveries during the Nuremberg trials. Nazi doctors were found to have committed horrific medical experimentation abuses against the inmates in concentration camps, who were exploited as research subjects. These experiments ranged from inflicting burns and gunshot wounds onto the subjects to test anti-infective agents, to immersing detainees in tubs of ice water for hours to assess the body's reaction to cold temperatures. The code attempted to set a standard for ethical behaviour when conducting human experimentation. It reflected the need for informed consent, condemned physical and mental suffering in experiments, stated that death and disability were not expected outcomes of experiments and affirmed that human subjects were to be protected from the slightest possibility of harm. The Nuremberg Code was a first legal attempt to grapple with ethical issues involved in human research.<sup>4</sup>

Soon thereafter in 1953, the Declaration of Helsinki was drafted by the World Medical Association. It reaffirmed the Nuremberg Code's stance on informed consent as well as allowed legal guardians to grant permission to enrol patients in therapeutic and non-therapeutic research. The Declaration of Helsinki also recommended written consent, a proposal not mentioned in the Nuremberg Code.<sup>4</sup>

While significant strides were occurring in the informed consent field, human subject safety in clinical trials was far from being guaranteed. The efforts to improve the ethical standards in clinical research took a significant step backwards when the details of Tuskegee Study came to light in 1972. Overseen by the Center for Disease Control and Prevention, this study, which began in 1932, exploited the lives of more than 400 African American sharecroppers suffering from syphilis by with-

holding medical treatment. These findings resulted in a considerable damage to the reputation of the medical research community and helped harbour irreconcilable mistrust from the public.<sup>4</sup>

In 1974, Congress passed the National Research Act in an effort to better protect human subjects. This act mandated that Institutional Review Boards (IRBs) be responsible for peer reviewing any research involving human subjects by requiring informed consents and reviewing the protocols of the experiments. This move was unprecedented since investigators never before had to seek approval of their own experiments.<sup>4</sup>

### Responsibilities of the IRB

An IRB may be created by independent firms or run by hospitals or universities. IRB is legally bound to be comprised of a wide variety of members ranging from scientists to lawyers to clergymen. Their responsibility lay in assessing the risks and benefits to ensure that the risks do not outweigh the potential benefits. They must also agree with the ethical standards met by the proposed study and ensure that the rights of vulnerable populations such as children, prisoners, pregnant women and mentally disabled persons are not compromised. The IRB also must be convinced that it is clinically appropriate to conduct the study. However, the IRB's responsibilities do not end there, since it is constantly updated on the study's progress and is notified of any changes in protocol during the course of the investigation.<sup>4</sup>

### Informed consent

#### Reason for informed consent

In many ways, informed consent serves as a patient's bill of rights. It is the patient's right to be completely informed about the study, to be presented with information that is understandable, and to agree to participate willingly without coercion. Therefore, it is imperative that guidelines exist which ensure safety and eliminate false pretences for human subjects. Protection of research participants is based on three principles: *Beneficence*, which implies that the goal of the study is to maximise the benefits to society while minimising the risks to study subjects; *Respect for persons*, which states that individuals must be respected regardless of their race, age, gender and socioeconomic status. This principle also asserts that certain individuals may be incapable of making decisions without the aid of a guardian or caregiver; and *Justice*, which

declares that risks and benefits must be shared equally among different types of people.<sup>4</sup>

### Consent procedures

To properly assess informed consent, the investigator or the coordinator of the research conducts the consent process and presents the study with elements pertaining to the consent. These elements of informed consent include: statement explaining the purpose of the research; the procedures involved and the duration of the study; description of foreseeable risks; description of benefits; disclosure of alternative treatments or procedures; explanation of compensation; list of contacts to help with questions; and a statement that participation is voluntary.<sup>4</sup>

### Responsibilities of the principal investigator

Although the patient agrees to participate in the study by signing the consent, informed consent does not absolve the physician/researchers from their responsibility to conduct safe and ethically sound practices. Informed consent also retains the patients'/subjects' right to file a lawsuit against the physician/researchers if wrong doing is suspected. The other responsibilities of the principal investigator include conducting the study in accordance to the approved protocol, maintaining adequate and accurate records and informing the IRB in cases of adverse experiences or deviations from the protocol.<sup>4</sup>

### Challenges of obtaining informed consent

#### Vulnerable populations

There are populations of research subjects that are for various reasons not considered to be fully autonomous and are thus designated by the FDA as "vulnerable population." There are many variables that would affect the level of autonomy, such as ethnicity, education level, age (children), mental capacity, pregnant women and incarcerated prisoners.

Ethnicity and cultural beliefs play a critical role in patient recruitment. In many cultural circles, the idea of primary intervention or prevention is a foreign concept. Many ethnicities do not seek medical help until issues have arisen. Furthermore, the concept of research is unfamiliar to them. Therefore, it is a challenge to convince this population to participate in research. Recruitment of subjects is

especially difficult in populations who share the cultural belief that women are considered property of their husband. This adds another problematic dimension since consent is not granted by the patient herself, but from her husband. In such a situation, proper communications play a key role in explaining written consent.<sup>3</sup>

A patient's educational level can also pose a significant challenge for subject recruitment. Potential participants who are illiterate would be unfairly excluded from research since written consent information would make it difficult to fully communicate all aspects of the study for these patients. Patients with below average educational levels would find it difficult to decipher the consent forms since they might not be familiar with the scientific terminology. Ultimately, many potential participants with lower literacy levels are excluded in clinical studies.<sup>3</sup>

In 2000, the FDA established Pediatric Rule which demanded that paediatric trials be conducted for all new medications used to treat conditions or diseases in children. This was to ensure that doctors receive appropriate information to safely prescribe new medications to children. With the surge in request for child participants for clinical research, new concerns and issues have risen regarding informed consent. Due to their legal inability to consent, children are thus part of a vulnerable population. Therefore, to protect the rights of children, the FDA has mandated that children must assent to participate in clinical trials, and their parents or guardians should provide fully informed consent.<sup>4</sup>

Patients with mental disabilities have impaired reasoning and judgment, and are thus considered a vulnerable population. This population includes patients with schizophrenia, manic depression, Alzheimer's disease and substance abuse. Since there are no federal regulations for the protection of human subjects with mental status impairment, the IRBs play a greater role in preserving the rights and safety of these subjects. If and when IRB deems a study fair and reasonable with benefits outweighing the possible risks, mentally ill patients are allowed to participate in the clinical trial. However, a legally competent adult must consent on behalf of the patient.<sup>4</sup>

While it is rare to find pregnant women in clinical trials, the Department of Health and Human Services (DHHS) code has limited their involvement in these studies. This vulnerable population is at potential risk for fetal toxicity as well as for maternal health complications. According to DHHS, pregnant women are only allowed to participate in trials if there is minimal risk to the fetus and if the study meets the mother's health needs. If the research is

only to benefit the fetus, then an informed consent from the father is needed as well. Consequently, pregnant women are also dissuaded from participating in all studies in their early stages due to their uncertain risks.<sup>4</sup>

Lastly, prisoners are considered to be a vulnerable population since they have limited choice and greater chances of being coerced into clinical trials. To ensure that proper ethical measures are taken, the IRBs are granted more responsibilities, which include making certain that risks/benefits are appropriate and that the selection of subjects is conducted in a fair manner. Additionally, federal regulation has mandated that at least one member on the IRB be a prisoner.<sup>4,7</sup>

### Emergency research

Voluntary informed consent is the cornerstone of federal policies regulating clinical trials. However, there are situations where a written informed consent is difficult to attain. Such is the case in a critically ill or injured patient who is unconscious or incompetent. Consequently, investigational treatment may be required immediately to resuscitate the patient under a life-threatening situation. However, without the informed consent, the potential life saving experimental therapy cannot be instituted. To better deal with this dilemma, the FDA and DHHS enacted the Final rule in 1996. This rule allowed for a slight exception to the requirements of informed consent when admitting critically ill patients in emergency clinical study. It stated that prior to the study, the IRB must determine that: patients have a life-threatening condition; the experimental treatment is unproven; research is necessary to assess the safety and effectiveness of the treatment; obtaining informed consent from the patient is unfeasible; participation may directly benefit the subjects; the waiver of informed consent is absolutely necessary for the clinical study; the investigator has agreed to contact all legal surrogates; and procedures are in place to allow family members to decline the subject's participation in the study. If these criteria are met, the investigators can proceed with the clinical study.<sup>1,2,6</sup>

Furthermore, additional safeguards have also been instituted due to the vulnerable state of these critically ill patients. This protection method, known as "community consultation," expects the investigators to publicly disclose the study plans, expected risks and benefits to the community. By constantly performing ongoing scientific monitoring on a current trial, community consultation can also determine whether the study should continue to proceed. The goal of this safeguard is to achieve better interaction between the community and the

investigators in the hope of better education about the proposed research for the public.<sup>1,2,6</sup>

### When informed consent is not necessary

While federal regulations have required informed consent on almost all clinical research, there are instances where it is not necessary. Informed consent is not required for research involving no more than minimal risk. Minimal risk is defined as risk that is comparable to those encountered in daily life. Informed consent is also not required in studies where the consent process may adversely impact the findings by disclosing too much information and creating a bias.<sup>8,9</sup>

As in the case of Final rule, if informed consent is waived in favour of initiating emergency treatment, consent can be deferred until later in the course of the study. This consent can be granted by the patient or his or her representative.<sup>1,2,6,5</sup>

### Conclusion

The recent history of human medical research necessitated proper protection of subjects' rights and safety. Through it all, informed consent emerged as a means to uphold ethical behaviour towards patients and to protect them in clinical studies. While it has served its purpose well, it is not without its shortcomings. There are still many challenges encountered in acquiring informed consent. Difficulties faced with vulnerable populations, especially with cultural biases and discrepancies in educational levels, warrant a simplification of the consent forms. Additionally, these challenges also highlight the need for greater emphasis on effective communications and on the consenting process. Therefore, alternative consenting procedures need to be explored as well.

### Acknowledgement

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## Review

## Informed consent: how much and what do patients understand?

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**KEYWORDS:**

Physician-patient relations;  
Disclosure;  
Patient rights;  
Bioethical issues;  
Consent document;  
Comprehension

**Abstract**

**OBJECTIVE:** We sought to evaluate the degree of patients' understanding of several aspects of the informed consent process for surgery and clinical research.

**METHODS:** We conducted a systematic search of PubMed (1961–2006) to identify relevant articles.

**RESULTS:** We retrieved 23 and 30 eligible for inclusion articles regarding informed consent for surgery and clinical research, respectively. Regarding surgery, adequate overall understanding of the information provided and of the risks associated with surgery was shown in 6 of 21 (29%) and 5 of 14 (36%) studies providing relevant data, respectively. Regarding clinical research, adequate understanding of the aim of the study, the process of randomization, voluntarism, withdrawal, and the risks and the benefits of treatment was shown in 14 of 26 (54%), 4 of 8 (50%), 7 of 15 (47%), 7 of 16 (44%), 8 of 16 (50%), and 4 of 7 (57%) of studies providing relevant data, respectively. Satisfaction by the amount of the given information was shown in 7 of 12 (58%) studies involving surgery and 12 of 15 (80%) studies involving clinical research.

**CONCLUSIONS:** Further attention should be drawn on enhancing patients' understanding regarding several components of the informed consent process for surgery and clinical research.

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A major evolution in the field of medicine over the past decades is the transition from a paternalistic way of approaching patients to a shared decision-making process. For patients to efficiently exercise their right of voluntarism, provision of adequate information is an important prerequisite.<sup>1</sup> There is no clear-cut consensus regarding the type and amount of information provided to patients receiving

various forms of treatment that could be considered adequate. This may be an even more controversial issue in the context of clinical research<sup>2</sup> because one of the main commitments of researchers is to generate scientifically valid data by closely adhering to study protocols. In this context, informed consent is an essential aspect of the doctor-patient relationship.

The process of informed consent includes the following 5 elements: voluntarism, capacity, disclosure, understanding, and decision.<sup>3</sup> Appropriate information given to a competent individual will promote understanding and, in this regard, sensible decision making without coercion. How-

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ever, the process of understanding involves the interaction of psychological and intellectual characteristics of an individual and depends on the educational status, the level of general knowledge, and personal attitudes, which are affected by the morals and customs of the society. The communication of medical information to patients is even more demanding because of the need to explain scientific issues with plain language. Physicians should also communicate medical information in a caring and compassionate way.<sup>4</sup> If these requirements are met, the clinician-patient relationship will be founded on trust and alliance.<sup>5</sup>

Many studies have examined the degree of patients' comprehension of several issues of the informed consent process within the settings of medical or surgical treatment as well as clinical research.<sup>6-8</sup> In an attempt to further evaluate the magnitude of patients' understanding of the several aspects of the informed consent process, we sought to systematically review the available evidence. We particularly focused on patients scheduled to undergo surgical interventions and on candidates of participation in clinical trials.

## Methods

### Literature search

We conducted a systematic search of PubMed (1961–2006) to identify relevant articles. We applied the search term “informed consent [ti].” In addition, we hand searched and reviewed the references of the selected articles. In Figure 1, we present the detailed process of screening for and identifying the eligible studies for inclusion in our review. Studies evaluating only the ability to recall the information that was provided during the informed consent process were excluded because recall into memory does not necessarily imply comprehension of the provided information. However, studies evaluating both recall and comprehension were included. Studies published in languages other than English were excluded.

### Data extraction

We evaluated the informed consent process regarding the main aspects of each of the 2 types of intervention (ie, surgery and participation in a clinical trial) that we addressed in this review. Specifically, for studies evaluating the informed consent process in patients scheduled to undergo a surgical procedure, we extracted and tabulated information on the following components of the informed consent process: (1) overall understanding of the provided information, (2) evaluation of the amount of given information, (3) comprehension of the risks and, (4) of benefits related to the surgical procedure.

For studies evaluating the informed consent process in participants in clinical research, we extracted and tabulated

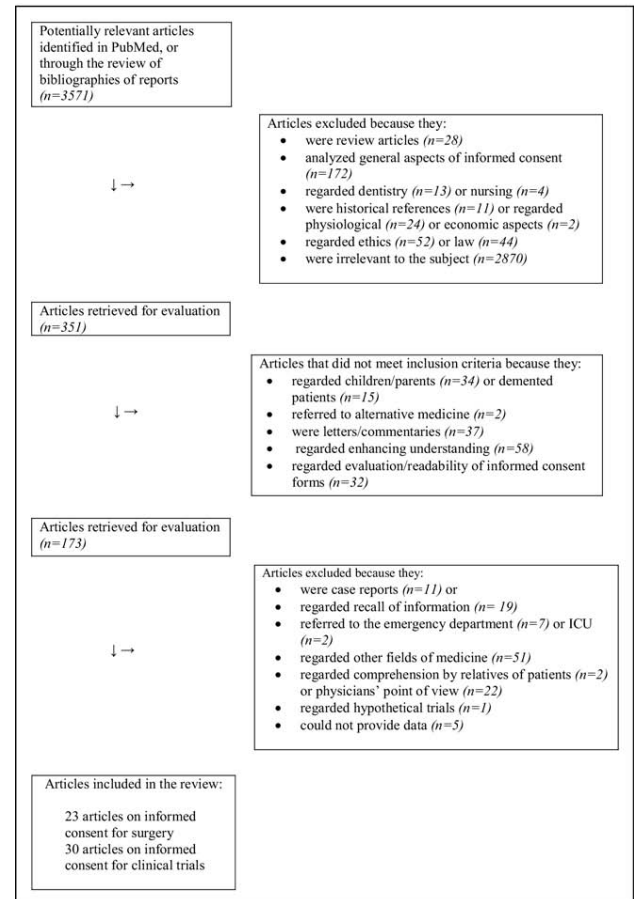


Figure 1 Flow diagram of reviewed articles.

information on the following components of the informed consent process: (1) comprehension of the aim of the study; (2) evaluation of the amount of given information; (3) understanding of the concepts and procedures of randomization, voluntarism, and study withdrawal; (4) comprehension of the risks and benefits of participating in a clinical trial, (5) understanding of the degree of therapeutic misconception (ie, the failure of the participants in clinical trials to conceive the distinction between clinical research and regular clinical practice), and (6) understanding of alternatives to treatment in the case of not participating in the clinical trial.

Specifically, for each of the previously mentioned components of the informed consent process in studies referring to surgery and clinical trials, we extracted data on the percentage of the included patients who had a level of understanding (or satisfaction, as applicable) for each of the components of the informed consent process that was graded in the various classification categories that were used in each study, along with the definitions of these categories. Additionally, we extracted data on the type of the surgical procedure or the characteristics of the clinical trial, the type of information provided to the patients, and the time spent on consultation regarding the informed consent process as well as the number of patients who evaluated the informed

**Table 1** Selected studies regarding the evaluation of the informed consent process for patients undergoing a surgical operation

Author/country/year of publication (ref)	Type of procedure	Number of patients (n)	Type of information provided to patients/Time spent on consultation/participation of trusted person	Timing of evaluation	Methods of evaluation/person who did the evaluation	Evaluation of the amount of provided information*	Understanding of given information*	Understanding the risks of operation*	Understanding the benefits of operation*
Ghulam/Switzerland—2006 <sup>9</sup>	Obstetric and gynecologic procedures	3,888 enrolled	Oral, written (leaflet)/NA/NA	Postoperatively before their hospital discharge	Questionnaire/Staff of the Swiss Patient Organization	Satisfied 2,224/2,332 (95) Too short 70/2332 (3) Excessive 38/2332 (2)† Detailed 25/150 (17)	Excellent 1,196/2,398 (50) Good 1,084/2398 (45) Neutral 101/2398 (4) 1,45/150 (97)§	Excellent 1,350/2470 (55) Good 986/2470 (40) Neutral 99/2470 (4) NA	Excellent 1,449/2,471 (59) Good 898/2,471 (36) Neutral 103/2,471 (4)† NA
Kušec/Croatia—2006 <sup>10</sup>	Laparoscopic cholecystectomy	150	Oral, written/NA/NA	Pre- or postoperatively	Questionnaire/NA				
Mishra/UK—2006 <sup>11</sup>	Coronary artery bypass grafting	40	Oral/NA/NA	Preoperatively, within 2 h of signing the CF	Questionnaire designed for face-to-face interviews/questionnaires were entered into computerized database	NA	Diagnosis Very good 6/40 (15) Good 12/40 (30) Just enough 18/40 (45)	Very good 2/40 (5) Good 2/40 (5) 10/40 (25)	Very good 6/40 (15) Good 17/40 (43) Just enough 13/40 (33)
Sahai/UK—2006 <sup>12</sup>	Laparoscopic urology	43	Oral, written (leaflet), audiovisual/NA/NA	28 d postoperatively	Telephone-based self-constructed patient-directed questionnaire, validated Client Satisfaction Questionnaire (CSQ-8)/independent individual of the team	NA	Leaflet 34/37 (92) Video 28/29 (95)	NA	NA
Dillon, Ireland/2005 <sup>13</sup>	Varicose vein operation	67	Oral, written (leaflet)/NA/NA	At least 14 d after outpatients' visit and preoperatively	Telephone based questionnaire/Single author	Happy with information given 55/67 (82) Enough information among patients who received the leaflet 39/50 (78)	NA	18/67 (27)	Unrealistic expectations of the benefits
Kessler/Switzerland—2005 <sup>14</sup>	Cholecystectomy	257	Interactive computer program, (11 min mean ±2), oral/NA	After hospital discharge, postoperatively	Questionnaire (excellent, good, undecided, poor or very poor)/NA	Excellent 184/257 (72) Good 63/257 (25)	Very satisfied 161/257 (63) Satisfied 96/257 (37)	NA	NA
Akkad/UK—2004 <sup>15</sup>	Elective obstetrics and gynecologic surgery	499	Oral, written/NA/yes	2 wks to 4 wks postoperatively	Questionnaire (yes or no)/questionnaires were entered into computerized database	Detailed 344/499 (69)	Overall satisfaction on ICP 399/499 (80) Handwritten material 342/414 (83)	NA	NA

(Continued on next page)

Table 1 (continued)

Author/country/year of publication (ref)	Type of procedure	Number of patients (n)	Type of information provided to patients/Time spent on consultation/participation of trusted person	Timing of evaluation	Methods of evaluation/person who did the evaluation	Evaluation of the amount of provided information* n/n (%)	Understanding of given information* n/n (%)	Understanding the risks of operation* n/n (%)	Understanding the benefits of operation* n/n (%)
Howlader/UK—2004 <sup>16</sup>	Cardiac Surgery	100	Oral, written (booklet)/NA/NA	5th day (median) postoperatively before their hospital discharge	Questionnaire/NA	Adequate 89/100 (89) Excessive 4/100 (4) Little 7/100 (7) NA	Met patients expectations 94/100 (94)	31/100 (31)	NA
Jebbin/Nigeria—2004 <sup>17</sup>	Elective surgical operation	150	Oral, 105/150 doctor 45/150 other <sup>¶</sup> /NA/yes <sup>¶</sup>	Pre- or postoperatively	Questionnaire/NA	NA	Diagnosis 112/150 (75) Nature of operation 114/150 (76)	55/150 (37)	NA
McKeague/New Zealand—2003 <sup>18</sup>	Elective general surgery (head, neck, breast, upper gastrointestinal, colorectal, other)	77	38 patients oral, 37 patients oral and written, 2 patients oral, written and video/NA/yes	Preoperatively (after admission to the ward) and postoperatively (within a week of their discharge, Completed by 42 patients)	Questionnaire (yes or no or short answer and 10-point linear analogue scale)/NA	Enough information Preoperative survey 38/77 (49) Postoperative survey 20/42 (48)	Preoperative survey 35/77 (45) Postoperative survey 18/42 (43)	46/77 (60)	68/77 (88)
Scanlan/Canada—2003 <sup>19</sup>	Cataract surgery	49	Oral/NA/NA	1 wk postoperatively	Questionnaire/NA	Enough 48/49 (97)	Diagnosis 28/49 (57) Treatment 39/49 (80) Alternatives 17/49 (35) NA	43/49 (88)	NA
Lloyd/UK—2001 <sup>20</sup>	Carotid endarterectomy	71	Oral/15-min consultation and graph presentation/NA	1 d preoperatively (1 month after consultation)	Multiple-choice questionnaire/NA	NA	NA	NA	Actual benefit 71/71 (100) Unrealistic benefits 39/71 (55)
Molina, United States—2001 <sup>21</sup>	Tubal ligation procedure	61	Written/NA/NA	NA	Questionnaire/principal investigator	NA	Alternative contraceptive methods 56/61 (91) Irreversibility of procedure 22/61 (36) 89/150 (59)	43/61 (70)	NA
Osuna, Spain—1998 <sup>22</sup>	Scheduled surgery	150	Oral/NA/NA	Pre- and postoperatively	Questionnaire/NA	NA	89/150 (59)	122/150 (81)	NA
Houghton, UK—1997 <sup>23</sup>	Minor or major surgical procedures	100	Oral (*outpatient consultation)/NA/NA	Post-operatively, within 6 wks of surgery	Questionnaire/NA	NA	95/100 (100) Misunderstanding as who will perform the surgery 50/100 (50)	84/100 (84)	NA

(Continued on next page)

Table 1 (continued)

Author/country/year of publication (ref)	Type of procedure	Number of patients (n)	Type of information provided to patients/Time spent on consultation/participation of trusted person	Timing of evaluation	Methods of evaluation/person who did the evaluation	Evaluation of the amount of provided information* n/n (%)	Understanding of given information* n/n (%)	Understanding the risks of operation* n/n (%)	Understanding the benefits of operation* n/n (%)
Kikuchi, Japan—1996 <sup>24</sup>	Cataract surgery	50	Oral, written, videotape/NA/yes	2 mo to 3 mo after education and 1 d preoperatively	Questionnaire/NA	NA	Relatively well 31/50 (62) Very well 15/50 (30) Not very well 4/50 (8)	Failure 43/50 (86) Become blind 36/50 (72) Death 29/50 (58)	NA
Sanwal/India—1996 <sup>25</sup>	Major abdominal operation	100	Oral/NA/NA	5th day postoperatively	Questionnaire/NA	NA	Good (total and partial) 70/100 (70) All 21/46 (46) Most 19/46 (41) Little 5/46 (11)	Total and partial 51/100 (51)	Total and partial 68/100 (68)
Saw/UK—1994 <sup>26</sup>	Transurethral Prostate resection	46	Oral, written/NA/NA	At least 6 h After the consent and preoperatively	Questionnaire/member of the medical team	Just right 43/46 (93) Too much 1/46 (2) Too little 2/46 (4) Enough information 76/111 (69)	NA	NA	NA
Williams/UK—1993 <sup>27</sup>	Elective surgery of various surgical specialties (ENT, urology, gynecology, ophthalmology, orthopedics, oral surgery, general surgery)	111	Oral/brief explanation/NA	One-half hour to 24 h preoperatively	Questionnaire/author	NA	45/111 (41)	NA	NA
Hutson/United States—1991 <sup>28</sup>	Total joint replacement	38	Oral, slide-tape presentation, joint and prosthesis model/(30 min to 60 min)/NA	Immediately after the consultation, preoperatively	Verbal questionnaire/educator	All questions answered 38/38 (100)	On diagnosis, treatment, and instructions 38/38 (100)	Major complication 23/38 (61)	Pain relief 25/38 (66) Improved function 20/38 (53) Increased range of motion 20/38 (53)
Askew/UK—1990 <sup>29</sup>	Cholecystectomy, hemicolectomy, inguinal hernia repair, truncal vagotomy and pyloroplasty	100 IG 42 CG 58	IG oral, written (information sheets) CG oral/NA/NA	2 d to 7 d postoperatively	Verbal questionnaire/NA	NA	IG 41/42 (97) CG 40/58 (69)	NA	NA
Wallace, UK—1986 <sup>30</sup>	Laparoscopy (infertility investigation, surgical sterilization)	1st study 131 2nd study 80	Oral, written (booklet only in 2nd study)/NA/NA	6 wk to 8 wk before hospitalization after consenting and on the morning of surgery	Multiple-choice questionnaire/Author	118/131 (90)+	Purpose of operation 6 wk to 8 wk 80/131 (61) Morning of surgery 62/131 (48)	Abdominal pain 117/131 (89) Time until returning to normal activities <40%	NA

(Continued on next page)

Table 1 (continued)

Author/country/year of publication (ref)	Type of procedure	Number of patients (n)	Type of information provided to patients/Time spent on consultation/participation of trusted person	Timing of evaluation	Methods of evaluation/person who did the evaluation	Evaluation of the amount of provided information* n/n (%)	Understanding of given information* n/n (%)	Understanding the risks of operation* n/n (%)	Understanding the benefits of operation* n/n (%)
Dunkelmann/UK—1979 <sup>31</sup>	Bowel surgery	16	Oral/NA/NA	Before surgery	Verbal questionnaire/Author	NA	Operation procedure 7/16 (44) Reason for operation 7/16 (44)	NA	NA

Abbreviations: CF, consent form; CG, control group; ENT, ear nose throat; GI, gastrointestinal; ICP, informed consent process; IG, informed group; NA, not available data.

\*The definitions of the various categories are those used in each study.

†Women assessed the extent of the CF.

‡Communication of the necessity of the operation.

§Patients' comprehension on written information was tested using the Cloze test procedure.

¶The source of knowledge of patients diagnosis were the doctor in 105 of 150 patients in the study while the remaining 45 patients found out their diagnosis from: husbands (4), overheard from doctors (2), nurses (1), not stated (38.)

+Women welcomed more information at each interview when asked at 6-8 weeks before hospitalization after consenting and on the morning of the operation.

consent process and the timing and methods used for the evaluation.

## Data analysis and synthesis

Because there are no uniform criteria for determining the quality of the informed consent process, we followed the categorization used in each of the included studies. To synthesize data across different studies, we focused on the percentage of patients who had a level of understanding (or satisfaction, as applicable) for a specific component of the informed consent process that was graded in the highest classification category among those used in each study. For matters of brevity, we refer to the highest ranked in each study level of understanding as "high" level of understanding. We synthesized the data from different studies in a qualitative manner. Specifically, we considered the quality of specific components of the informed consent process as adequate if more than 80% of the participants had a level of understanding (or satisfaction, as applicable) graded in the highest classification category. If 50% to 80% or less than 50% of the participants had a level of understanding (or satisfaction, as applicable) graded in the highest classification category, we considered the quality of the informed consent process as moderate or inadequate, respectively.

## Results

### Informed consent for surgery

**Characteristics of selected studies.** A total of 3,571 potentially relevant articles were initially retrieved from the PubMed search. With regard to informed consent in the field of surgery, we selected as eligible for inclusion in our review 23 studies,<sup>9-31</sup> of which the main characteristics and findings are presented in Table 1. Almost half (11/23) were conducted in the United Kingdom. Five of the overall 23 selected studies involved informed consent for abdominal surgery,<sup>10,14,25,29,31</sup> 4 studies referred to obstetric and gynecologic operations,<sup>9,15,21,30</sup> 2 studies involved cardiac surgery,<sup>11,16</sup> 2 other studies eye surgery (cataract),<sup>19,24</sup> and 2 more studies involved urologic surgery,<sup>12,26</sup> informed consent for surgery for carotid stenosis,<sup>20</sup> varicose veins,<sup>13</sup> and joint replacement<sup>28</sup> was evaluated in 1 study for each category, respectively, whereas 5 studies evaluated informed consent for mixed types of operations.<sup>17,18,22,23,27</sup> The number of patients evaluated ranged from 16 to 77 in 11 studies and 100 to 499 in 11 studies, whereas 1 study enrolled 3,888 patients of whom 2,332 to 2,471 were evaluated for the various outcomes.

The information regarding the informed consent process was communicated by both verbal explanation and written materials in 9 studies, by verbal explanation alone in 8 studies, by written materials alone in 1 study, by verbal explanation or written materials along with video presenta-

**Table 2** Synthesis of data from different studies regarding the evaluation of the various components of the informed consent process for surgery or participation in clinical trials

Components of the informed consent process	Studies showing different levels of understanding or satisfaction for the components of informed consent		
	Adequate,* N/n (%)†	Moderate,* N/n (%)†	Inadequate,* N/n (%)†
<b>Surgery</b>			
Evaluation of the amount of provided information	7/12 (58) <sup>9,13,16,19,26,28,30</sup>	3/12 (25) <sup>14,15,27</sup>	2/12 (17) <sup>10,18</sup>
Understanding of given information	6/21 (29) <sup>10,12,16,23,28,29</sup>	9/21 (43) <sup>9,14,15,17,19,22,24,25,30</sup>	6/21 (29) <sup>11,18,21,26,27,31</sup>
Understanding the risks of operation	5/14 (36) <sup>19,22-24,30</sup>	5/14 (36) <sup>9,18,21,25,28</sup>	4/14 (29) <sup>11,13,16,17</sup>
Understanding the benefits of operation	2/6 (33) <sup>18,20</sup>	3/6 (50) <sup>9,25,28</sup>	1/6 (17) <sup>11</sup>
<b>Clinical trials</b>			
Evaluation of the amount of provided information	12/15 (80) <sup>35-39,42,45,46,48,56,57,59</sup>	2/15 (13) <sup>53,55</sup>	1/15 (7) <sup>51</sup>
Aim of the study	14/26 (54) <sup>34-39,41,42,50-54,57</sup>	6/26 (23) <sup>32,46,47,56,59,60</sup>	6/26 (23) <sup>33,43,45,48,49,55</sup>
Randomization	4/8 (50) <sup>40,46,54,58</sup>		4/8 (50) <sup>36,37,41,42</sup>
Voluntarism	7/15 (47) <sup>35,36,39-41,49,59</sup>	7/15 (53) <sup>34,37,38,46,53,56,58</sup>	1/15 (7) <sup>57</sup>
Withdrawal	7/16 (44) <sup>36,39,40,45,46,49,50</sup>	7/16 (44) <sup>37,41,47,56,59-61</sup>	2/16 (13) <sup>53,57</sup>
Risks from treatment	8/16 (50) <sup>37,47,49-51,54,56,59</sup>	4/16 (25) <sup>33,35,52,57</sup>	4/16 (25) <sup>32,45,46,61</sup>
Benefits from treatment	4/7 (57) <sup>49,50,56,61</sup>	2/7 (29) <sup>38,46</sup>	1/7 (14) <sup>33</sup>
Therapeutic misconception	1/15 (7) <sup>44</sup>	5/15 (20) <sup>35,39,42,43,59</sup>	9/15 (60) <sup>37,38,46,48,49,51,55,56,58</sup>
Alternatives to treatment	2/7 (29) <sup>38,46</sup>	3/7 (43) <sup>35,47,36</sup>	2/7 (29) <sup>49,56</sup>

\*Adequate, moderate, and inadequate level of understanding or satisfaction is used by the authors of this review to denote that >80% to 100%, 50% to 80%, and 0% to <50% of the participants in a study had a level of understanding or satisfaction for a specific component of the informed consent process graded in the highest ranking category among those used in the study.

†Numbers and percentages refer to studies.

tion in 3 studies, and by verbal explanation along with computer or slide presentation in 2 studies. Among the included studies, 4 reported the assistance of a trusted person during the informed consent process.<sup>15,17,18,24</sup> The timing of the assessment of the informed consent process was after surgery in 9 studies, before surgery in another 9 studies, either before or after surgery in 4 studies, and it was not reported in the remaining study. The evaluation of the informed consent process was based on questionnaires in all studies. In 18 studies,<sup>9-11,14-27,30</sup> written questionnaires were handed to patients (in 2 of these studies,<sup>20,30</sup> the questionnaires consisted of multiple-choice questions); in 3 studies,<sup>28,29,31</sup> verbal questionnaires were used; and in 2 studies,<sup>12,13</sup> the questionnaires were telephone based. The person who did the evaluation was a member of the research team in 7 of 23 studies,<sup>13,21,26-28,30,31</sup> an independent evaluator in 4 of 23 studies,<sup>9,11,12,15</sup> and in 12 studies this aspect was not mentioned. Table 2 summarizes the data obtained for different studies evaluating specific components of the informed consent process. Main relevant data are presented in detail later.

**Understanding by patients of the information provided during informed consent.** The percent of patients who reported having a high level of understanding of the information given during the informed consent process was

above 90% in 6 of 21 studies.<sup>10,12,16,23,28,29</sup> In 1 study, the number of patients who conceived the provided information was similar regardless of whether this evaluation was performed preoperatively or postoperatively (51% vs 45%, respectively).<sup>18</sup> Conversely, another study revealed a reduction in the percentage of patients who understood the provided information, from 61% to 48%, when this was assessed immediately after consenting (6 weeks to 8 weeks before hospitalization) compared with when this was assessed on the morning of surgery.<sup>30</sup>

**Amount of information provided.** Regarding the evaluation of the quantity of information provided, 82% to 100% of patients considered it satisfactory in 7 of 12 studies.<sup>9,13,16,19,26,28,30</sup> Notably, the understanding of the given information was adequate in 2 and moderate in 3 of the 6 studies in which the satisfaction by the amount of the given information was also adequate.<sup>9,16,19,28,30</sup> In addition, in 1 study, the same proportion of patients (approximately 47%) considered the amount of the provided information enough, regardless if this was evaluated preoperatively or postoperatively.<sup>18</sup>

**Understanding the risks and benefits of surgery.** In 5 of 14 studies, the percentage of patients who had a high level of comprehension of the overall or certain risks entailed by

**Table 3** Selected studies regarding the evaluation of the informed consent process for participants in clinical trials

Author/country/year of publication (ref)	Trial purpose/population	Number of patients evaluated (n)	Type of information provided to patients/Time spent on consultation	Number of patients who read the consent form (n)	Timing of evaluation	Methods of evaluation/person who did the evaluation
Griffin/United States—2006 <sup>32</sup>	RCT on HDL cholesterol raising treatment/males with heart diseases and low HDL levels	1789	Oral, written (CF) to the patient and a witness	NA	At the end of a 5 yrs trial	Multiple-choice answers coded as correct or incorrect/NA
Guarino/United States—2006 <sup>33</sup>	Informed consent trial within a "parent" clinical illness trial/males with chronic illnesses	1086-at baseline	Written (CF)	NA	0, 3 mo, 6 mo, 12 mo	Questionnaire, investigator or participant-developed (questions with 2-4 point response scales and open ended question)/NA
Joseph, Haiti—2006 <sup>34</sup>	HIV vaccine clinical trial/HIV seronegative adults	250	ES 1 oral, videotape (8 minutes) ES 2 one-on-one meeting/30 min	ES 1 365 patients. ES 2 250 patients	After participants' completion of second education session	Verbal questionnaire (true/false and open-ended questions) administered by a psychologist 2nd evaluation after additional educational session for those who failed 1st/research staff
Barrett, United States—2005 <sup>35</sup>	Oncology clinical trials/adult cancer patients	8	Written (CF)	8/8 (100)	NA	Quality of informed consent questionnaire (QuIC) written at an eighth-grade reading level/NA
Moodley/South Africa—2005 <sup>36</sup>	Influenza vaccine RCT/elderly participants	334	Oral (3 sessions including a verbal explanation and revision of a leaflet), written (take home leaflet with a Flesch score of 46)	322/334 (96)	4 mo to 12 mo after completion of trial	Interviews based on a semistructured questionnaire/NA
Pace/Thailand—2005 <sup>37</sup>	Part of an ethics substudy of ESPRIT trial/adults HIV-positive with CD4 cell count $\geq 300/\text{mm}^3$	141	Oral (group and individual discussion), written (CF)/2 h/translation in Thai	138/141 (98)	After consenting and before randomization assignment	Multiple-choice questions (33 minutes average interview)/ESPRIT coordinating center
Sugarman/United States—2005 <sup>38</sup>	Clinical trial assessing quality of ICP of a "parent" trial/elderly patients	627	Oral (parent trial)	NA	Telephone interview following completion of "parent" trial ICP	Questionnaire (IC aggregate score and Therapeutic misconception aggregate score) and open verbatim responses/member of the project team
Lynöe/China—2004 <sup>39</sup>	Research ethical study on a cadmium pollution epidemiological project/Rice farmers	624	Oral	NA	1 mo after the epidemiological project NA	Questionnaire-based interview survey-use of interpreters/NA
Simon/United States—2004 <sup>40</sup>	Oncology clinical trial P III/adult cancer patients	79	Oral/54.73 min (mean)	45/50 (90)	NA	Semistructured interview/three research assistants
Wang/China—2004 <sup>41</sup>	Vitamins and folic acid trial for neural tube defects prevention/Pregnant women	247†	Oral (1 year education campaign), various written material, audiovisual	NA	NA	Quantitative questionnaire and qualitative interview (common items in both for evaluation of consistency, quality control in both, uniform trained interviewers)/trained interviewer and one of the researchers
Pope/Canada—2003 <sup>42</sup>	Assessment of participants understanding on ICP/patients selected from Card, RHEU, OPH trials	190 card 84 RHEU 74 OPH 32	Oral, written (Letter of information, CF)/help from others	141/172 (82)	Between 2 mo and 5 yrs after signing the consent form	Written questionnaire/NA
Pentz/United States—2002 <sup>43</sup>	Endostatin trial PI/cancer patients	Pre-ICP 79 Post-ICP 21	36/76 (47%) from media coverage, 35% from their doctors	21/21 (100)	NA	Structured interview by telephone or in person with open-ended questions/two principal investigators and a third one who resolved conflicts

Evaluation of the amount of provided information* n/n (%)	Understanding by study participants of:							
	Aim of the study/CF*	Randomization* N/n (%)	Voluntarism* N/n (%)	Withdrawal* N/n (%)	Risks from treatment* n/n (%)	Benefits from treatment^ n/n (%)	Therapeutic misconception* n/n (%)	Alternatives to treatment* n/n (%)
NA	1157/1789 (65)	NA	NA	NA	556/1789 (31)	NA	NA	NA
NA	Completely 371/1070 (35) mostly 431/1070 (40) somewhat 228/1070 (21)	NA	NA	NA	Completely 495/1070 (50) mostly 317/1070 (32) somewhat 144/1070 (14)	Completely 475/1000 (48) mostly 337/1000 (34) somewhat 164/1000 (16)	NA	NA
NA	1 st evaluation 186/250 (74) 2nd evaluation 39/47 (83)† experimental AIDS vaccine 162/250 (65)	NA	189/250 (76)	NA	NA	NA	NA	NA
Satisfactory 8/8 <sup>100</sup>	8/8 (100)	not done	8/8 (100)	NA	4/8 (50)	NA	4/8 (50)	5/8 (63)
Satisfactory 327/334 <sup>98</sup>	318/334 (95)	67/319 (21)	331/334 (99)	289/332 (87)	NA	NA	NA	191/329 (58)
Satisfactory 140/141 <sup>99</sup>	124/141 (88)	43/141 (31)	103/141 (73)	96/141 (71)	138/141 (98)	NA	13/141 (9)	NA
Satisfactory 596/627 <sup>95</sup>	558/627 (89)	NA	420/627 (67)	NA	NA	404/627 (64)	38/627 (6)	596/627 (95)
Quite good 510/624 (82) good 26/624 (4) average 4/624 (.6)	562/624 (90)	NA	537/624 (86)	543/624 (87)	NA	NA	474/624 (76)	NA
NA	NA	49/53 (92)	54/54 (100)	50/53 (94)	NA	NA	NA	NA
NA	179/217 (83)	57/217 (26)	205/217 (95)	144/217 (66)	NA	NA	NA	NA
In total 171/184 <sup>93</sup>	183/186 (98)	In total 64/165 (39) Card 41/84 (49) RHEU 18/56 (32) OPH 5/25 (20)	NA	NA	NA	NA	In total 89/177 (50)	NA
NA	Post-ICP 9/21 (43)	NA	NA	NA	NA	NA	13/20 (65)	NA

(Continued on next page)



Table 3 (continued)

Author/country/year of publication (ref)	Trial purpose/population	Number of patients evaluated (n)	Type of information provided to patients/Time spent on consultation	Number of patients who read the consent form (n)	Timing of evaluation	Methods of evaluation/person who did the evaluation
Cohen/United States—2001 <sup>44</sup>	Immunotherapy trial P I-b/patients with metastatic renal cell carcinoma or melanoma	46	NA	46	At the beginning and end of treatment	Questionnaire with a 10-item scale correlated significantly with the life orientation test (measurement of treatment-specific optimism)/NA
Gotay/Hawaii—2001 <sup>45</sup>	Prostate cancer prevention trial/elderly healthy men	69	Oral (extended counseling)	47/69 (68)	2 y after joining a 7-yr study	Mailed questionnaires including closed-ended and free-response questions/NA
Joffe/United States—2001 <sup>46</sup>	Cancer treatment clinical trial P. I, II, III/adult cancer patients	205 P I 50 P. II 103 P. III 54	Discussion, written (pamphlet)/1 h or longer (50% of discussions)	170/205 (84) (careful reading)	3 d to 14 d after signing consent	Mailed questionnaires/Investigators
Fortney/United States-Africa-Latin America—1999 <sup>47</sup>	Contraceptive clinical trial/healthy young women	70	Written (Spanish or English or local language forms)	NA	0 d to 289 d	Questionnaire based interviews/principal investigator at each site
Hutchison/UK—1998 <sup>48</sup>	Chemotherapy trial PI/cancer patients	28	Oral, written	28	2 wk to 4 wk after consenting	Interview based on a questionnaire with closed-ended questions/NA
Daugherty/United States—1995 <sup>49</sup>	P I investigational agents trial/adult cancer patients	27	Oral	27	Before receiving any P I agents	Structured interview with open- and closed-ended questions (standardized survey form)/NA
Lawson, United States—1995 <sup>50</sup>	Assessment of patients understanding on CF terminology/mostly adult chronic disease patients	86	Written (cover letter)	86/86 (100)	NA	Mailed survey consisting on 15 open-ended questions testing knowledge of common words from consent forms/NA
Négrier/France—1995 <sup>51</sup>	Interleukin-2 P II trial/cancer patients	24	Written (information sheet, CF), oral/25 min (mean)	24	Immediately after receiving information	Written questionnaire/Investigators
Tankanow/United States—1992 <sup>52</sup>	Investigational drug studies/In- and out-patients	98	Oral, written (CF)	98	72 h after signing consent	20-min interview based on a questionnaire/NA
Lynöe/Sweden—1991 <sup>53</sup>	Gynecologic clinical trial/Young women with acute Fallopian tube inflammation	43	Oral, written	42/43 (98)	18 mo after the end of the trial	Mailed questionnaire/NA
Dunbar, United States/1989 <sup>54</sup>	Diabetes control and complications trial (DCCT)/IDDM patients	278	Audiovisual, written, interview±	NA	After educational process and 1 yr participation/family member involved in the educational process	14-item multiple-choice questionnaire/20-item Family Understanding and Expectation questionnaire/NA
Rodenhuis/the Netherlands/1984 <sup>55</sup>	P I anticancer agent clinical trial/adult patients with advanced cancer	10	Oral (3 separate sessions)	48	4 wks after consenting and starting of treatment/close relative or trusted friend involved in the educational process	Structured interviews preferably at the patient's home/trained observer (dependent)
Penman/United States—1984 <sup>56</sup>	Investigational chemotherapy trial P II or III/adult cancer patients	144	Oral (individual consultation time), written	NA	1 d to 21 d after consenting	Structured interview/computer coding of quantitated responses
Goodman/UK—1984 <sup>57</sup>	Two studies assessing ventilatory effects of postoperative analgesia/surgical patients	ret 14 sub 18	Written (leaflet), oral	14/14 (100) 18/18 (100)	Upon completion of postoperative phase of the study/discussion of the information with relatives	Mailed questionnaire of yes/no answers, multiple-choice answers and spontaneous comments/NA

Evaluation of the amount of provided information* n/n (%)	Understanding by study participants of:							
	Aim of the study/CF*	Randomization* N/n (%)	Voluntarism* N/n (%)	Withdrawal* N/n (%)	Risks from treatment* n/n (%)	Benefits from treatment^ n/n (%)	Therapeutic misconception* n/n (%)	Alternatives to treatment* n/n (%)
NA	NA	NA	NA	NA	NA	NA	39/46 (85)	NA
"Just right" 30/32 <sup>94</sup>	29/67 (43)	NA	NA	64/69 (93)	11/69 (16)	NA	NA	NA
satisfied 185//205 <sup>90</sup>	153/205 (75)/173/205 (86)	48/53 (91)	151/205 (74)	183/204 (90)	75/205 (37)	145/205 (71)#	31/205 (15)	170/204 (83)
NA	United States 3/5 (60) Afr. 8/8 (100) LA I 3/8 (38) LA II 2/8 (25)	NA	NA	United States 12/15 (80) Afr. 3/17 (18) LA I 11/19 (58) LA II 9/19 (47)	United States 4/5 (80) Afr. 7/8 (88) LA I 5/8 (62) LA II 8/8 (100)	NA	NA	United States 2/5 (40) Afr. 5/8 (63) LA I 8/8 (100) LA II 8/8 (100)
Sufficient 25/28 <sup>89</sup>	All 10/28 (36) Most 14/28 (50) Some 4/28 (14)	NA	NA	NA	NA	NA	Cure 2/28 (7) A bit better 9/28 (32) not worse 16/28 (57)	NA
NA	Determine dosage 9/27 (33)	NA	22/27 (81)	23/27 (85)	26/27 (96)	23/27 (85)	6/27 (22)	8/27 (30)
NA	74/86 (86)	NA	NA	83/86 (81)	77/86 (90)	80/86 (93)	NA	NA
No additional information needed 8/22 <sup>36</sup>	24/24 (100)	NA	NA	NA	24/24 (100)	NA	2/21 (10)	NA
NA	Full or most 81/98 (83)	NA	NA	NA	77/98 (79)	NA	NA	NA
very good 15/22 <sup>68</sup> , good 7/22 <sup>32</sup>	37/43 (86)	NA	34/43 (79)	19/43 (44)	NA	NA	NA	NA
NA	267/278 (96)	278/278 (100)	NA	NA	Standard treatment group 98% experimental treatment group 94%	NA	NA	NA
Sufficient 8/10 <sup>80</sup>	4/10 (40)	NA	NA	NA	NA	NA	2/10 (20)	NA
Sufficient 118/144 (82) Insufficient 20/144 <sup>14</sup> Excessive 6/144 <sup>4</sup>	By physician 99/144 (69) In consent form 84/144 (58)	NA	115/144 (80)	By physician 104/144 (72) In consent form 91/144 (63)	By physician 143/144 (99) In consent form 115/144 (80)	By physician 117/144 (81) In consent form 50/144 (35)	62/144 (43)	By physician 68/144 (47) In consent form 23/144 (16)
Satisfied 30/32 <sup>94</sup>	13/14 (93) 17/18 (94)	NA	2/14 (14) 9/18 (50)	3/14 (21) 5/18 (28)	14/14 (100) 1/16 (6)	NA	NA	NA

(Continued on next page)

**Table 3** (continued)

Author/country/year of publication (ref)	Trial purpose/population	Number of patients evaluated (n)	Type of information provided to patients/Time spent on consultation	Number of patients who read the consent form (n)	Timing of evaluation	Methods of evaluation/person who did the evaluation
White/United States—1984 <sup>58</sup>	Chemotherapy trial/women with advanced breast cancer	75	Written (different length CFs)	75/75 (100)	Right after reading CF	Written questionnaire/NA
Riecken/United States—1982 <sup>59</sup>	Biomedical Research trial/male adult patients	156	Oral, written (CF)/ < 15 min to > 30 min	Written+or oral <sup>+</sup>	NA	Interviews (global ratings and detailed scoring scheme)/ principal investigators
Taub/United States—1981 <sup>60</sup>	RCT to evaluate participants comprehension on the ICP/elderly adults	87	Oral, written	87	Immediately after information given	Questionnaires with multiple-choice and fill in questions/experimenter
Bergler/United States—1980 <sup>61</sup>	Anti-hypertensive drug trial/adult male hypertensive patients	39	Written (CF)/10 min to 15 min	39	1 st and 90th day of enrollment	interview and 9-question multiple-choice questionnaire/NA

the surgical procedures was above 80% (81%–89%).<sup>19,22–24,30</sup> Notably, 2 studies evaluating informed consent for cardiac surgery found that patient understanding of the risks of the operation was inadequate.<sup>11,16</sup> In contrast, 2 other studies evaluating informed consent for eye (cataract) surgery found that the understanding of risks of the operation was adequate.<sup>19,24</sup> Regarding the understanding of the potential benefits conferred by surgery, 88% to 100% of patients in 2 of 6 studies reported a high level of comprehension.<sup>18,20</sup>

### Informed consent for clinical research

**Characteristics of selected trials.** Among the 3,571 articles retrieved from our PubMed search, 30 studies relevant to this review providing data on informed consent in the setting of clinical trials were identified.<sup>32–61</sup> The main characteristics and findings of these studies are presented in Table 3. The included studies were conducted in the United States,<sup>18</sup> China,<sup>2</sup> the United Kingdom,<sup>2</sup> South Africa,<sup>1</sup> Canada,<sup>1</sup> Haiti,<sup>1</sup> Thailand,<sup>1</sup> France,<sup>1</sup> The Netherlands,<sup>1</sup> and Sweden.<sup>1</sup> Of note, 1 study provided data from 3 different regions: United States, Latin America, and Africa. Eleven studies involved cancer patients (in 5 studies recruited in phase I trials), whereas various fields of medicine were involved in the rest of the studies. The number of participants evaluated for their understanding of different aspects of the informed consent process was between 8 and 98 subjects in 17 studies, 141 and 627 subjects in 11 studies, and 1,070 and 1,789 subjects in 2 studies. The information

provided to participants was in both oral and written form in most of the relevant studies (12/29), in written form alone in 7 studies, in oral form alone in 6 studies, and 3 studies used audiovisual methods in addition to written or oral communication. In 1 study<sup>43</sup> the information was provided either orally by physicians or through media coverage.

The evaluation of the informed consent process was based on questionnaires and interviews. In particular, 21 studies evaluated the informed consent process with questionnaires, of which 5 used open-ended questions,<sup>33,34,38,43,50</sup> 4 multiple-choice questions,<sup>32,37,54,61</sup> 2 both closed- and open-ended questions,<sup>45,49</sup> 1 closed-ended questions alone,<sup>48</sup> 1 multiple-choice and fill-in questions,<sup>60</sup> in 3 studies evaluation was based on mailed questionnaires,<sup>46,53,57</sup> and for 5 studies the details about the form of the written questionnaires used were not available.<sup>35,42,44,51,58</sup> In 8 studies, a semistructured interview or an interview based on a questionnaire was used for the evaluation,<sup>36,39,40,47,52,55,56,59</sup> and in 1 additional study the evaluation was based on both a quantitative questionnaire and a qualitative interview.<sup>41</sup> The person who did the evaluation was a member of the research team in 11 of 30 studies,<sup>34,38,40,41,43,46,47,51,55,59,60</sup> an independent evaluator in 2 of 30 studies,<sup>37,56</sup> and in 17 studies this aspect was not mentioned.

Table 2 summarizes the data obtained for different studies evaluating specific components of the informed consent process. Main relevant data are presented in detail later.

Evaluation of the amount of provided information* n/n (%)	Understanding by study participants of:							
	Aim of the study/CF*	Randomization* N/n (%)	Voluntarism* N/n (%)	Withdrawal* N/n (%)	Risks from treatment* n/n (%)	Benefits from treatment <sup>^</sup> n/n (%)	Therapeutic misconception* n/n (%)	Alternatives to treatment* n/n (%)
NA	NA	Long 24/25 (96) medium 21/25 (84) short 19/25 (76)	47/75 (62)	NA	NA	NA	Long 9/25 (36) medium 9/25 (36) short 4/25 (16)	NA
Satisfied 100/112 (89)	112/156 (72)	NA	106/112 (95)	90/112 (80)	101/112 (90)	NA	84/112 (75)	NA
NA	61/87 (70)	NA	NA	66/87 (76)	NA	NA	NA	NA
NA	NA	NA	NA	30/39 (77)	11/39 (28)	37/39 (95)	NA	NA

Abbreviations: AFR, Africa; CARD, cardiology; CF, consent form; ES, education session; HDL, high density lipoprotein; ICP, informed consent process; IDDM, insulin-dependent diabetes mellitus; LA, Latin America; NA, not available data; OPH, ophthalmological; P, phase; RCT, randomized controlled trial; RET, retrospective; RHEU, rheumatological; SUB, subsequent.  
+In some cases, written explanations provided to patients were read to them by the investigator.  
\*The definitions of the various categories are those used in each study.  
†Second evaluation was performed on the participants who failed (failures) after an additional education session.  
‡Two hundred seventeen participants completed a quantitative questionnaire while the remaining 30 participants completed a qualitative interview.  
#Participants understood that there may not be any direct medical benefit to them from their participation in the trial.  
±In addition to audiovisual, oral (interview) and written information (informed consent form, handbook, dictionary of tests and terms) provided, several other tools were used such as: self-predictors of adherence, knowledge tests, behavioral practice, and family questionnaire.

**Understanding the aim of the study and evaluation of the amount of information.** A high level of understanding of the aim of the clinical trial was reported by 83% to 100% of the participants in 14 of 26 of the reviewed studies.<sup>34-39,41,42,50-54,57</sup> In nearly all the studies (12 of 15) reporting data on the evaluation of the quantity of information provided during informed consent, 82% to 100% of the subjects participating in clinical trials considered that the amount of information was satisfactory.<sup>35-39,42,45,46,48,56,57,59</sup> Notably, the understanding of the aim of the study was adequate in 7 of the 12 studies (58%) in which the satisfaction by the amount of the given information was also adequate.<sup>35-39,42,57</sup>

**Understanding the concepts of randomization, voluntarism, and withdrawal.** Only 8 studies provided data on the understanding of the concept of randomization.<sup>36,37,40-42,46,54,58</sup> In 4 of these studies, a relatively high proportion of participants (91%–100%) had a high level of understanding of the meaning of the randomization procedure.<sup>40,46,54,58</sup> The concept of voluntarism was highly understood by 81% to 100% of the participating subjects in 7 of 15 studies.<sup>35,36,39-41,49,59</sup> Another important aspect of clinical trials is the right of the individuals to withdraw consent of participation at any time. Respectively, more than 81% of the participants in 7 of 16 clinical trials highly understood the concept of withdrawal from the trial.<sup>36,39,40,45,46,49,50</sup>

**Understanding the risks and benefits of the participation in clinical trials.** The potential complications and risks during participation in clinical trials were highly understood

by 90% to 100% of the participants in 8 of 16 studies.<sup>37,47,49-51,54,56,59</sup> Data regarding the comprehension of potential benefits conferred by the participation in clinical trials were provided in 7 studies.<sup>33,38,46,49,50,56,61</sup> The proportion of subjects who highly understood the respective benefits was between 81% and 95% in 4 studies,<sup>49,50,56,61</sup> in one of these studies, the proportion of individuals who highly understood the potential benefits depended on the method of communication of the relevant information,<sup>56</sup> which was higher when this information was communicated by the physician (81%) than when solely reported in the consent form (35%).

**Therapeutic misconception and understanding treatment alternatives.** Regarding the issue of therapeutic misconception, in 1 of 15 studies, 85% of subjects participating in the clinical trial seemed to expect that they would be successfully treated.<sup>44</sup> The alternatives to the suggested treatment were highly understood by 83% to 95% of the individuals in 2 of 7 studies.<sup>38,46</sup>

## Comments

The review of the available evidence regarding informed consent for surgical interventions showed that adequate overall understanding by the patients of the various aspects of the informed consent process was reported in less than one third of the studies. It should be mentioned, however, that there are some limitations in the evaluation of the above parameter. First of all, the definition of adequate under-

standing is often arbitrary and remains controversial.<sup>62</sup> Furthermore, patients may consider themselves being well informed about issues regarding the surgical procedure while this may not actually hold true. The educational level of the patients is also an important factor affecting the level of understanding because patients with a lower educational level may feel embarrassed to ask explanatory questions.

It has been suggested that providing verbal explanations along with written material and/or multimedia presentations enhances the patients' ability to comprehend the provided information.<sup>63</sup> However, our review does not provide adequate data to address this issue. The quantity of the information provided could also be important in this regard. The patients' evaluation of the informed consent process may also be influenced by the temporal relation of the evaluation to the informed consent process as well as to surgery. A lack of adequate time for comprehension of the provided information may result in poorer findings regarding the efficacy of the informed consent process.<sup>64</sup> Conversely, the evaluation of patients undergoing surgery at the time of discharge may result in a more favorable assessment of the informed consent process.<sup>16</sup> Moreover, the evaluation of the efficacy of the informed consent process at the time of discharge incorporates the patients' own experience of the surgical procedure and postoperative course and thus may be considered more representative. In such a setting, however, recall bias may compromise the quality of the evaluation. Additionally, patients may not be able to accurately estimate the risk of death attributed to the procedure at the time of discharge.<sup>11</sup>

In most studies included in this review regarding surgery and providing relevant data, adequate patient satisfaction by the amount of provided information resulted in adequate or moderate understanding of the respective information. However, exceptions to this association were observed,<sup>26</sup> which highlight the importance of properly communicating all relevant information to the patients.

The findings of this review indicate that an appreciable proportion of patients may not comprehend the risks of the proposed surgical interventions. It has been suggested that this could be attributed to emotional factors.<sup>65</sup> The latter parameter may also relate to the degree of risk associated with the type of procedure in regard. A potential way to overcome this problem is to provide information about risks along with information on how to cope with them postoperatively.<sup>30</sup> Moreover, the presence of a person trusted to the patient, such as a relative or a friend, during the informed consent process may support the patient emotionally and also aid the patient in understanding the information provided. However, the 4 studies included in this review that used such a strategy reported variable levels of overall understanding of the given information by the patients scheduled for surgery.<sup>15,17,18,24</sup> Another noteworthy observation in this review is that patients do not seem to understand the benefits that derive from the proposed surgery.

This probably reflects the overall unawareness about their disease and the potential complications.<sup>66</sup>

Regarding the informed consent process in clinical trials, an important consideration arising from this review is that participants may not clearly understand the investigative nature of clinical trials. Specifically, adequate comprehension of the aim of the clinical trials was achieved in half of the reviewed studies that provided relevant data. The provision of an adequate amount of information to the patients was important in this regard in most of the relevant studies. Moreover, sufficient understanding cannot be directly attributed to the type of information provided. It seems that the main principles for achieving adequate comprehension by participants include using simple language on information sheets,<sup>67,68</sup> and providing enough time to evaluate this information along with the opportunity to clarify any misunderstanding. This is indicated by a study in which better comprehension was achieved for all outcomes in the subset of patients who were informed by physicians rather than by simply reading the informed consent form.<sup>56</sup> Furthermore, the findings of studies performed in countries under development, such as Thailand,<sup>37</sup> Haiti,<sup>34</sup> and South Africa,<sup>36</sup> show that despite the lower literacy level and socioeconomic status in these settings, satisfactory comprehension may be achieved when subjects are informed in a proper way.<sup>69</sup>

The concepts of randomization, voluntarism, and withdrawal are fundamental in clinical trials. In this review, the opportunity to withdraw consent seems to be well understood by the participants. Regarding the important issue of voluntarism, however, half of the studies that provided relevant data revealed an adequate rate of understanding among the participating subjects. This could be related to patients' preference to defer the decision of participation to their physicians<sup>70</sup> or to fear of being deprived of adequate clinical care. However, it should be mentioned that the concept of randomization was highly understood by most subjects in only half of the studies that provided relevant data.

Moreover, risks and benefits of participation as well as alternatives to treatment appeared to have been comprehended by a relatively small number of participants in clinical trials. Subjects entering a clinical trial seem to expect substantial benefit to be conferred by the novel treatments. Especially cancer patients may place all of their hopes for improvement on their chance of receiving a novel, potentially effective treatment.<sup>71,72</sup> That contributes to the "therapeutic misconception," which is an extremely intricate issue. In this regard, it has been considered that providing more detailed information about concealed allocation could only lead to the refusal of participation.<sup>73</sup> Especially in phase I cancer trials, for which dose determination is the primary purpose, subjects may consider their participation as associated with several risks.<sup>74</sup> Researchers may face an ethical dilemma about how much precision of information is appropriate for patients.<sup>75</sup> Sufficient attention should be

given to clarify the issue of randomization, if applicable, and to ensure that in the case that one of the tested treatments proves superior, no patient group would be deprived of the therapeutic benefits. Benefits of participation in clinical trials, such as the provision of continuous medical care and the potential benefits from novel scientific developments may be emphasized.<sup>76</sup>

An integral limitation of our study is that standards for the proper methodology of the evaluation of the informed consent process in general or of specific components of this process in particular have not been so far well established.<sup>62</sup> The studies included in this review used variable methodology and criteria for the evaluation of the informed consent process. Specifically, they used mainly interviews or questionnaires, consisting of multiple-choice, closed-ended, or open-ended questions. The latter type of questions, particularly asking the participants to explain in their own words what has been communicated, appears to be a good method to validate their level of understanding.<sup>8,77</sup> It should be mentioned, however, that the main purpose of our study was not to identify the optimal methodology and criteria for evaluating the quality of the informed consent process.

In conclusion, available evidence from the reviewed studies regarding the granting of informed consent by patients to undergo surgical interventions or to participate in clinical trials suggests that although most patients perceive the amount of provided information as sufficient, the degree of actual understanding of the various components of the informed consent process may not in fact be satisfactory. This shows the need for physicians to communicate relevant information to patients in a comprehensive manner in addition to the use of well-designed tools, such as written material or audiovisual media, which may increase the degree of patients' understanding of the information provided.

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หัวข้อ : Breaking bad news

## การแจ้งข่าวร้าย

### Breaking Bad News

รองศาสตราจารย์นายแพทย์ สุพจน์ พงศ์ประสพชัย

ภาควิชาอายุรศาสตร์ คณะแพทยศาสตร์ศิริราชพยาบาล

#### ความสำคัญ

การแจ้งข่าวร้าย (breaking bad news) เป็นทักษะการสื่อสารอันหนึ่งที่มีความสำคัญอย่างยิ่งของแพทย์ในเวชปฏิบัติ เนื่องจากแพทย์ต้องเกี่ยวข้องกับการแจ้งข่าวร้ายแก่ผู้ป่วยและญาติเสมอ ๆ ไม่ว่าจะเป็นการแจ้งผลการวินิจฉัยโรค การสืบค้นที่ผู้ป่วยต้องได้รับ การรักษา ผลการรักษา และพยากรณ์โรค ข่าวร้ายเป็นสิ่งที่ไม่มีผู้ป่วยคนใดปรารถนา แพทย์เองก็ไม่พึงปรารถนาและบางท่านอาจรู้สึกว่าการแจ้งข่าวร้ายเป็นเสมือนการทำร้ายผู้ป่วยและพยายามหลีกเลี่ยงไม่ยอมทำ แต่ข่าวร้ายคือความจริงและเป็นประโยชน์อย่างยิ่งยวดต่อผู้ป่วยในอนาคต การหลีกเลี่ยงการแจ้งข่าวร้ายจึงอาจเป็นการทำร้ายผู้ป่วยทางอ้อมและมักก่อผลเสียต่อผู้ป่วยในที่สุด

การแจ้งข่าวร้ายเป็นการสื่อสารแบบหนึ่ง แต่มีเรื่องของอารมณ์และความรู้สึกของผู้รับสารร่วมด้วยอย่างมาก แพทย์ที่ต้องแจ้งข่าวร้ายจึงต้องประณีตในการทำ วัตถุประสงค์ความรู้ มีความรู้ ทักษะ และต้องใส่ใจหัวใจเข้าไปในการทำด้วยเสมอ การแจ้งข่าวร้ายไม่มีเทคนิคมาตรฐาน แต่มีหลักการที่ขอเพียงแค่แพทย์เข้าใจ นำไปฝึกฝน และใส่ใจเข้าไปในการทำก็มักจะทำได้ดี ทักษะการแจ้งข่าวร้ายเป็นทักษะสำคัญที่แพทย์ขาดไม่ได้แต่แปรเปลี่ยนที่กลับมีการสอนทักษะการแจ้งข่าวร้ายในโรงเรียนแพทย์ค่อนข้างน้อย ทำให้แพทย์จำนวนมากไม่มั่นใจและพยายามหลีกเลี่ยงเพราะเกรงว่าถ้าทำไม่ได้จะเกิดผลร้ายต่อผู้ป่วยตามมามากกว่าผลดีและกลัวว่าญาติผู้ป่วยอาจไม่เข้าใจหรือไม่พอใจ เป็นต้น ความกลัวเหล่านี้เป็นมิจฉาภิทธิ เพราะทำให้ผู้ป่วยที่เราต้องการรักษาประโยชน์กลับกลายเป็นเสียประโยชน์ในที่สุด

#### ควรแจ้งข่าวร้ายแก่ใคร ผู้ป่วยหรือญาติ หรือทั้งคู่?

##### หลักการ

ในสังคมโลกตะวันตกนั้นการแจ้งข่าวร้ายเป็นสิ่งที่ต้องแจ้งกับผู้ป่วยโดยตรงตามหลักของสิทธิผู้ป่วย (patient autonomy) แต่ในสังคมโลกตะวันออกรวมทั้งประเทศไทยนั้น กลับกลายเป็นว่าแพทย์จำนวนมากเลือกที่จะแจ้งข่าวร้ายแก่ญาติมากกว่า (ยกเว้นโรคเอดส์เพียงโรคเดียวที่แพทย์จะแจ้งแก่ผู้ป่วยเท่านั้น) โดยเฉพาะถ้าเป็นข่าวที่ร้ายมาก ๆ เช่น โรคร้ายแรงถึงชีวิต หรือโรคมะเร็ง เป็นต้น ด้วยเหตุผลต่าง ๆ นานา เช่น กลัวผู้ป่วยจะรับไม่ได้ (แต่กลับคิดว่าญาติจะรับได้) กลัวผู้ป่วยทรุด (ซึ่งส่วนใหญ่ไม่เป็นความจริง ถ้าแจ้งข่าวร้ายอย่างถูกต้อง ผู้ป่วยอาจซึมเศร้าไปช่วงหนึ่ง แต่ในระยะยาวผู้ป่วยมักค่อย ๆ ดีขึ้น) แต่เหตุผลเล็ก ๆ ที่แพทย์มักกังวล คือ แพทย์กลัวว่าถ้าบอกข่าวร้ายไปแล้วผู้ป่วยแยลง ญาติจะไม่เข้าใจและจะมาเอาเรื่องแพทย์ในภายหลัง



ดังนั้นเมื่อคำนึงถึงสิทธิผู้ป่วยและประโยชน์ต่อผู้ป่วยในระยะยาวแล้ว การแจ้งข่าวร้ายควรให้แก่ผู้ป่วยเป็นหลัก ยกเว้นผู้ป่วยไม่ต้องการรู้ ไม่มีสติสัมปชัญญะ หรือแพทย์คิดว่าข่าวร้ายนั้นอาจไม่มีประโยชน์ใด ๆ ต่อผู้ป่วยอีกแล้ว เช่น ผู้ป่วยอายุมาก ๆ และโรคร้ายเป็นมากจนน่าจะอยู่ได้อีกไม่นาน ผู้ป่วยอยู่บนเตียงไม่สามารถทำอะไรได้นัก เป็นต้น ข้อมูลในผู้ป่วยไทยที่เป็นโรคมะเร็งที่โรงพยาบาลศิริราช พบว่าประมาณร้อยละ 90 อยากให้แพทย์บอกการวินิจฉัยตามจริง ในขณะที่ประมาณร้อยละ 10 อยากให้แพทย์บอกกับญาติมากกว่า (ข้อมูลจากอาจารย์นายแพทย์ไพโรจน์ สินลารัตน์ สาขาวิชาเคมีบำบัด โรงพยาบาลศิริราช) ข้อมูลนี้ทำให้แพทย์ต้องทำความเข้าใจใหม่ว่าแท้จริงแล้วผู้ป่วยไทยส่วนใหญ่ก็ยังต้องการให้แพทย์แจ้งข่าวร้ายแก่ตนตามจริงมากกว่า

### ประโยชน์จากการที่ผู้ป่วยได้ทราบความจริง

ข้อดีของการที่ผู้ป่วยทราบความจริงมีมากมาย ได้แก่

1. **ผู้ป่วยจะได้วางแผนชีวิตของตนเอง** เมื่อข่าวร้ายนั้นมีผลอย่างมากต่ออนาคต แพทย์หรือญาติที่ไม่ใช่ผู้ป่วย ย่อมไม่มีทางรู้ว่าผู้ป่วยต้องการอะไรและกำลังวางแผนชีวิตอะไรอยู่
2. **ผู้ป่วยจะสามารถเป็นผู้ตัดสินใจเลือกการสืบค้นหรือการรักษาได้ด้วยตนเอง** ในกรณีที่เป็นการตรวจหรือรักษาที่มีความเสี่ยง (เช่น การผ่าตัด การให้เคมีบำบัด เป็นต้น) หรืออาจตัดสินใจได้ยาก (เช่น การเลือกที่จะใส่ท่อหายใจหรือการปฏิบัติภารกิจชีวิต เป็นต้น) ผู้ป่วยย่อมเป็นผู้ตัดสินใจได้ดีที่สุด
3. **ไม่มีความลับระหว่างแพทย์กับผู้ป่วยหรือญาติกับผู้ป่วย** ทำให้การพูดคุยเป็นไปได้อย่างเปิดเผย ไม่ต้องงุบงิบลับ ๆ ล่อ ๆ ไม่ต้องคอยระวังว่าความลับจะแตก *ไม่เคยมีแพทย์หรือญาติสามารถปิดบังความลับต่อผู้ป่วยได้* เพราะผู้ป่วยจะรู้ตัวเองเสมอ ทั้งจากอาการของตนเองที่ทรุดลงเรื่อย ๆ จากท่าทีของแพทย์ ท่าทีของญาติ และจากการหลุดปากของคนรอบตัว การที่ผู้ป่วยมักรู้ความจริงเองแต่ไม่ครบถ้วนอาจทำให้ผู้ป่วยเข้าใจผิด ๆ และมักกังวลไปในทางที่ร้ายกว่าความเป็นจริง ผลคือ *ผู้ป่วยต้องเผชิญกับความทุกข์อย่างโดดเดี่ยว เพราะไม่สามารถคุยกับใคร ไม่สามารถปรึกษาซักกับใคร และไม่สามารถร้องไห้กับใคร* เพราะคนรอบข้างพยายามปิดบังไม่พูดถึงเรื่องนี้ ทำให้บรรยากาศในครอบครัวเต็มไปด้วยความเงิบเหงาและความอึดอัด (conspiracy of silence) ทั้ง ๆ ที่เวลานี้เป็นเวลาผู้ป่วยต้องการคนที่รักมาช่วยรับฟังและให้การประคับประคองอย่างที่สุด

### ผู้ป่วยน่าจะเป็นผู้เลือกว่าอยากให้แพทย์แจ้งข่าวแก่ตนเองหรือแก่ใคร

ผู้ป่วยแต่ละคนมีพื้นฐานและบริบทของตนเอง ผู้ป่วยจึงเป็นผู้ที่เหมาะสมที่สุดที่จะเลือกว่าอยากให้แพทย์แจ้งข่าวแก่ตนเองโดยไม่ต้องบอกญาติ หรือให้แจ้งญาติโดยไม่ต้องบอกตน หรืออยากให้แจ้งแก่ทั้งตนและญาติพร้อม ๆ กัน ซึ่งแพทย์สามารถส่งเสริมความต้องการนี้ได้โดยการคุยกับผู้ป่วยและญาติ ตั้งแต่การมาตรวจครั้งแรก ๆ หรือก่อนจะรู้ผลตรวจ เช่น การพูดว่า

“คุณสมชาย (ผู้ป่วย) ครับ ผมขอปรึกษาหน่อยครับ อยากทราบว่าครั้งหน้าถ้าได้ผลตรวจแล้ว อยากให้หมอแจ้งกับคุณสมชายโดยตรง หรืออยากให้แจ้งกับญาติ ๆ หรืออยากมาฟังด้วยกันทั้งหมดครับ” เป็นต้น

### หากญาติกังวลไม่อยากจะแพทย์แจ้งข่าวร้ายแก่ผู้ป่วยจะอย่างไร

บ่อยครั้งญาติจะแอบมาบอกแพทย์ก่อนว่า ถ้าเป็นโรคร้าย (เช่น มะเร็ง) ไม่ให้บอกผู้ป่วยเป็นอันขาดเพราะกลัวผู้ป่วยจะทรุด ความหวังโยของญาติแบบนี้ก็เป็นที่เข้าใจได้ แต่ส่วนใหญ่เกิดจากความเข้าใจผิด แพทย์ไม่จำเป็นต้องทำตามใจญาติ แต่ควรพูดคุยกับญาติอย่างเข้าใจ ชื่นชมในความหวังโยของญาติ ถามเหตุผลที่คิดเช่นนั้น แกไขความเข้าใจผิด เช่น กลัวผู้ป่วยจะทรุด เป็นต้น บอกประโยชน์ที่ผู้ป่วยจะได้หลังจากทราบความจริงตามเหตุผลต่าง ๆ ที่กล่าวแล้วข้างต้น และบอกญาติให้คลายกังวลว่าแพทย์มีกระบวนการแจ้งอย่างข่าวร้ายอย่างระมัดระวัง ไม่ต้องวิตก จากประสบการณ์ของผู้เขียนพบว่าญาติมักเข้าใจและยินดีให้บอกความจริงแก่ผู้ป่วยเกือบทุกราย แต่หากญาติยังไม่เข้าใจและยินกรานไม่ให้บอกผู้ป่วย ผู้เขียนแนะนำว่าอาจทำตามความต้องการของญาติไปก่อน ไม่ควรหักหาญน้ำใจ แล้วค่อย ๆ พยายามอธิบายใหม่ในครั้งต่อ ๆ ไป หรืออาจบอกญาติว่าแพทย์จะลองเลียบเคียงถามจากผู้ป่วยดูว่าพอจะทราบอะไรมาแล้วบ้าง ซึ่งถ้าพบว่าผู้ป่วยพอทราบมาก่อนแล้ว ก็สามารถอธิบายญาติให้ยอมรับว่าผู้ป่วยพอรู้แล้ว ไม่น่าต้องปิดบังอะไรอีก หรือเมื่อถึงจุดที่ต้องมีการตัดสินใจที่ยาก เช่น เลือกจะให้เคมีบำบัดหรือผ่าตัดหรือไม่ เป็นต้น ซึ่งแพทย์น่าจะถือโอกาสนี้ชี้ให้ญาติเห็นว่าถ้าผู้ป่วยทราบความจริง ผู้ป่วยน่าจะเลือกเองได้ดีที่สุด ดังนั้นน่าจะแจ้งผู้ป่วย เป็นต้น

### เทคนิคการแจ้งข่าวร้าย

การแจ้งข่าวร้ายมีหลายเทคนิค แต่เทคนิคที่มีผู้แนะนำค่อนข้างมาก<sup>1</sup> และผู้เขียนเองนิยมใช้คือเทคนิค “SPIKES” ซึ่งเสนอโดย Buckman และคณะ<sup>2</sup> ซึ่งมีรายละเอียดดัง ตารางที่ 1

#### ตารางที่ 1 ขั้นตอนการแจ้งข่าวร้ายโดยวิธี SPIKES

<b>S</b>	Setting up
<b>P</b>	Patient perception
<b>I</b>	Invitation of bad news
<b>K</b>	Knowledge
<b>E</b>	Emotion
<b>S</b>	Strategy

#### S (Setting up)

หมายถึง การเตรียมการ แพทย์ควรต้องมีเวลาเพียงพอ ไม่เร่งรัด สถานที่พูดคุยควรมีความเป็นส่วนตัว เงียบสงบพอสมควร ควรมีที่นั่งสำหรับผู้ป่วยและญาติทุกคน (ไม่ควรยืนคุย) พยายามตัดสิ่งรบกวน เช่น แจ้งบอกพยาบาลล่วงหน้าไม่ให้ใครมารบกวนขณะกำลังคุยกับผู้ป่วย แพทย์ควรปิด

โทรศัพท์มือถือระหว่างคุย ควรมีกระดาษที่ขูเสมอในกรณีที่ผู้ป่วยอาจร้องไห้ แพทย์เองก็ต้องทำจิตใจตนเองให้สงบเช่นกัน ควรทบทวนประวัติและผลตรวจต่าง ๆ ของผู้ป่วยให้เข้าใจก่อน

### P (Patient perception)

หมายถึง การประเมินว่าผู้ป่วยพอทราบอะไรมาบ้างแล้ว แพทย์ควรเริ่มการสนทนาด้วยการทักทาย แนะนำชื่อตนเอง ทานชื่อผู้ป่วย และถามชื่อญาติ (ควรถามชื่อญาติทุกคนได้จะดีที่สุด ไม่ควรเรียกญาติว่า “ญาติ”) ควรมี small talk เล็กน้อยเพื่อสร้างความคุ้นเคย แล้วค่อยประเมินว่าผู้ป่วยพอทราบอะไรมาบ้างแล้ว เช่น

“คุณสมชายครับ ครั้งที่แล้วที่คุณสมชายมาตรวจเพราะเรื่อง..... จำได้มั๊ยครับว่าผมได้อธิบายอะไรให้คุณสมชายฟังบ้างครับ..... หมอว่าหมอสงสัยว่าเป็นอะไร?.....ลองเล่าให้หมอฟังหน่อยครับ”

หากพบว่าผู้ป่วยพอทราบบ้างแล้ว แต่ดูกังวลหรือกลัว ก็ควรถามลงลึกลงไปว่าเหตุผลที่กังวลและอาจให้ความหวังเสริมไปได้เลยในขั้นตอนนี้ เช่น

“คุณสมชายกลัวเป็นมะเร็ง เพราะอะไรครับ?”

“ใช่ครับ เรากำลังสงสัยว่าโรคหรืออาจเป็นเนื้องอกมะเร็ง แต่ไม่ว่าจะเป็นอะไรก็รักษาได้ครับ”

ถ้าผู้ป่วยบอกว่ายังไม่ทราบ หรือบอกว่าแพทย์ไม่ได้บอกอะไร อาจเกิดจากแพทย์คนที่แล้วไม่ได้อธิบายเลยจริง ๆ ก็ต้องคุยอธิบายผู้ป่วยใหม่ แต่ถ้าคิดว่าแพทย์น่าจะอธิบายมาเพียงพอแล้ว ก็อาจเกิดจากผู้ป่วยทราบแต่พยายามปฏิเสธ (denial) ต่อสิ่งที่แพทย์พูดในครั้งที่แล้ว แพทย์ก็ควรเข้าใจ อย่าโกรธผู้ป่วยว่าทำไมไม่เข้าใจยาก ควรถามคำถามเจาะลงไป (explore) เพื่อหาสาเหตุ ทำให้แพทย์สามารถอธิบายผู้ป่วยได้ เช่น

“คุณสมชายกำลังกังวลอะไรหรือเปล่าครับ ช่วยเล่าให้หมอฟังหน่อยครับ”

### I (Invitation of bad news)

หมายถึง การเชื้อเชิญและเตรียมให้ผู้ป่วยทราบว่าแพทย์กำลังจะบอกข่าวร้าย เช่น

“คุณสมชายครับ วันนี้เราจะมาฟังผลตรวจกันนะครับ”

“คุณสมชายครับ คุณสมชายอยากให้หมอบอกผลการตรวจมากน้อยแค่ไหนครับ”

“ตอนหมอบอกผลตรวจ คุณสมชายอยากให้..(ญาติ)..อยู่ด้วยมั๊ยครับ”

ถ้าข่าวร้ายนั้นค่อนข้างร้าย ก่อนจะบอกข่าวร้าย แพทย์ควรมี “warning shot” ก่อนเสมอ เช่น

“ผลชิ้นเนื้อออกมาไม่ค่อยดีครับ....”

“ผลออกมาไม่เป็นดังที่เราหวังครับ.....”

หลังจากนั้นจึงบอกข่าวร้าย

### K (Knowledge)

หมายถึง การให้ข่าวร้าย (ไม่ใช่การให้ความรู้ทางการแพทย์) ได้แก่ ตัวข่าวร้ายที่แพทย์ต้องการแจ้งนั่นเอง ควรบอกอย่างชัดเจน ตรงไปตรงมา ไม่กำกวม หลังจากบอกข่าวร้ายแล้วผู้เชี่ยวชาญบางท่าน (รวมทั้งผู้เขียน) มักให้ความหวังแก่ผู้ป่วยตามมาเสมอ เช่น

“ผลเป็นมะเร็งครับ..... แต่มีทางรักษา (ช่วย) ได้ครับ” เป็นต้น

ข้อผิดพลาดที่พบบ่อย ๆ คือ หลังจากแจ้งข่าวร้ายและแพทย์พยายามให้ความหวังแล้ว ถ้าโรคนั้นรักษาไม่หาย แพทย์มักกังวลใจแล้วพูดต่อมากเกินไปจนกลายเป็นทำลายความหวังนั้นเสียเอง ซึ่งจะทำให้ผู้ป่วยรู้สึกแย่งเพราะสิ่งที่จะเป็นความหวังนั้นถูกทำลายไป เช่น

“ผลเป็นมะเร็งครับ แต่มีทางรักษาได้...ถึงแม้การรักษาจะได้อผลไม่ 100% และไม่หายขาด”

“ผลเป็นมะเร็งครับ พอมมีทางรักษาได้... แม้การรักษาจะควบคุมโรคให้ดีขึ้นได้ระดับหนึ่ง”

“ผลเป็นเลือดบวก (เอตส์) ครับ แต่มียารักษาได้ ถึงแม้จะไม่หาย ได้แค่ชะลอก็ตาม” เป็นต้น

สาเหตุคือ แพทย์มักรู้สึกที่ไม่ควรพูดให้ความหวังมากจนลืมนึกไป มิเช่นนั้นจะเหมือนการโกหก และภายหลังผู้ป่วยจะมาเอาเรื่อง ซึ่งที่แท้จริงแล้วเราไม่ได้โกหก การที่เราบอกว่ามีทางช่วย มีทางรักษานั้นเป็นความจริงแท้แน่นอน แพทย์ควรบอกความจริงเท่าที่มีประโยชน์ต่อผู้ป่วย ไม่จำเป็นต้องพูดทุกอย่างจนหมดเปลือก ผู้เขียนพบว่าผู้ป่วยส่วนใหญ่หลังจากได้ฟังข่าวร้ายแล้วได้ความหวัง มักไม่ซักไซ้แพทย์ต่อว่ารักษาได้หายขาดได้หรือไม่ คาดว่าเพราะผู้ป่วยเองก็อยากถนอมความหวังเอาไว้ ไม่อยากซักถามต่อที่อาจจะเป็นการทำลายความหวังนั้นเสียเอง แต่บางครั้งญาติเองต่างหากที่ไม่เข้าใจและพยายามถามแพทย์ว่า “จะหายขาดหรือไม่?” ซึ่งบางครั้งเหมือนซักใบให้เรือเสีย ผู้เขียนเองมักไม่ตอบคำถามนี้แต่จะใช้การพูดยืนยันเหมือนเดิมว่า “รักษาได้ครับ”

การพูดในขั้นตอนนี้ แพทย์ควรพูดให้ช้า ให้ชัด อาจหยุดเพื่อถามความเข้าใจผู้ป่วยเป็นระยะๆ (tell-ask-tell) ต้องคอยสังเกตปฏิกิริยาของผู้ป่วยตลอดเวลา ยังไม่ควรพูดข้อมูลทางการแพทย์มากมาย เช่น รายละเอียดของโรคหรือการรักษาในขั้นตอนนี้

## E (Emotion)

หมายถึง การรับมือกับอารมณ์ของผู้ป่วย เนื่องจากผู้ป่วยหลังจากได้รับข่าวร้ายจะมีการตอบสนองแตกต่างกันไป เช่น ผู้ป่วยอาจร้องไห้ โกรธ ปฏิเสธ ตอรอง ซ็อก เจ็บใจ หรืออาจยอมรับได้เป็นอย่างดี แพทย์มักรู้สึกถ้าผู้ป่วยที่มีปฏิกิริยา ร้องไห้ โกรธ ปฏิเสธ ตอรอง ซ็อก เจ็บใจ แปลว่าผู้ป่วย “รับไม่ได้” แสดงว่าการแจ้งข่าวร้ายนี้ไม่ประสบความสำเร็จ ซึ่งเป็นความเข้าใจที่ผิด เพราะปฏิกิริยาทั้งหมดนี้ล้วนเป็นสิ่งปกติ เป็นกลไกป้องกันทางจิตใจของผู้ป่วยเอง ดังนั้นหน้าที่ของแพทย์คือต้องเข้าใจและช่วยส่งเสริมกลไกเหล่านี้ให้ไปสู่การทำให้ผู้ป่วยยอมรับในที่สุด ได้แก่

ผู้ป่วยที่ร้องไห้ (crying) แพทย์มักกลัวและทำอะไรไม่ถูก จึงมักรีบยับยั้งหรือปลอบผู้ป่วยเร็วเกินไป เช่น พูดว่า “อย่าร้องไห้.....ใจเย็น ๆ.....ไม่ต้องคิดมาก” เป็นต้น ซึ่งเป็นการทำร้ายผู้ป่วยทางอ้อม เพราะการร้องไห้ทำให้ความทุกข์ที่ท่วมท้นในใจของผู้ป่วยหลังไหลออกมา ผู้ป่วยจะดีขึ้นและสงบลงเอง

จนพร้อมจะรับฟังแพทย์ต่อได้เอง ที่จริงผู้ป่วยที่ร้องไห้กลับเป็นผู้ป่วยที่รับมือง่ายกว่าอย่างอื่น สิ่งที่แพทย์ควรทำคือ ควรเจียบให้ผู้ป่วยร้องไห้สักพัก ยื่นกระดาษทิชชูให้ (ไม่ควรใช้ผ้าเช็ดหน้าของแพทย์) หรือการสัมผัสโดยแตะมือผู้ป่วยเบาๆ (ไม่ควรแตะสูงเกินไปหรือต่ำกว่าเอว) โดยอาจไม่ต้องพูดอะไรเลย

**ผู้ป่วยที่โกรธ (anger)** แพทย์มักกลัวที่สุด ผู้ป่วยอาจกล่าวโทษแพทย์ กล่าวโทษโรงพยาบาลอื่น หรือโทษโชคชะตา เป็นต้น แพทย์ควรเข้าใจ ไม่ควรรีบยับยั้งผู้ป่วย เช่น “ใจเย็นๆ”, “ค่อยๆ พูดค่อยๆ จา” “หมอเข้าใจความรู้สึกของคุณ” หรือรีบแก้ตัว เป็นต้น เพราะผู้ป่วยจะยิ่งรู้สึกว่าแพทย์ไม่เข้าใจ แพทย์ควรให้ผู้ป่วยระบาย (release) สิ่งที่อยู่อกออกมาผู้ป่วยจะดีขึ้น เช่น พูดว่า “พูดออกมาเลยครับ หมอกำลังฟังครับ” เมื่อผู้ป่วยระบายความโกรธออกมาแล้วจนเริ่มสงบแล้วแพทย์อาจพูดว่า “หมอขอบคุณที่คุณสมชายบอกให้หมอรบาย” หรือ “หมอเสียใจกับเรื่องที่เกิดขึ้น” เป็นต้น ไม่ควรไปแก้ตัวต่าง ๆ นานา หรือแก้ตัวแทนผู้อื่นก่อนจะให้ผู้ป่วยระบายความโกรธออกเสียก่อนเพราะจะทำให้ผู้ป่วยโกรธยิ่งขึ้น

**ผู้ป่วยที่ปฏิเสธ (denial)** เช่น “ไม่น่าใช่嘛ครับ.....ผลผิดพลาดหรือเปล่าครับ.....หมอดูอีกทีมั๊ยครับ” เป็นต้น ผู้ป่วยมักไม่ได้ต้องการคำตอบจริง ๆ แพทย์ไม่ควรไปตอบหรือย้ำผู้ป่วยว่า “ใช่แน่นอนครับ.....ผลไม่ผิดแน่ครับ.....ไม่ต้องตรวจใหม่ครับ.....” เป็นต้น เพราะจะเป็นการย้ำแผลที่ผู้ป่วยปฏิเสธให้เจ็บยิ่งขึ้น แพทย์ควรรับฟัง แสดงความเห็นใจ เช่น การสัมผัส แสดงความเห็นใจ (empathy) บอกผู้ป่วยว่า เช่น “หมอเข้าใจ” “คุณสมชายคงไม่ยากเชื่อ” เป็นต้น

**ผู้ป่วยที่ต่อรอง (bargaining)** ยังลังเลหรือสองจิตสองใจ แพทย์ควรรับฟังและแสดงต่อผู้ป่วยว่า ท่านเข้าใจ ให้เวลาผู้ป่วย บางครั้งก็ต้องนัดแนะมาใหม่ภายหลัง

**ผู้ป่วยที่ช็อก (shock) หรือเงียบไป (silence)** กลับเป็นผู้ป่วยที่รับมือยากกว่าแบบอื่น เพราะดูยากว่าผู้ป่วยคิดอะไรอยู่ ควรให้ผู้ป่วยเงียบอยู่กับตนเองสักครู่ แล้วจึงกระตุ้นผู้ป่วยโดยการสัมผัส แล้วถามหยั่ง (probing) ดู เช่นพูดว่า “ดูคุณสมชายเงียบไป รู้สึกอย่างไรครับ บอกหมอหน่อยครับ” เป็นต้น ผู้ป่วยก็จะแสดงออกมาว่าที่จริงมีปฏิกิริยาอย่างไร แพทย์ก็จะรับมือได้ง่ายขึ้น

### S (Strategy)

หมายถึง การวางแผนต่อไป หลังจากรับมือกับอารมณ์ของผู้ป่วยและผู้ป่วยสงบแล้ว แพทย์สามารถถามผู้ป่วยได้ว่าพร้อมที่จะให้แพทย์พูดคุยต่อเรื่องแนวทางต่อไปเลยหรือไม่ เช่น

“คุณสมชายครับ พร้อมที่จะคุยกับหมอต่อมแล้วมั๊ยครับ”

ถ้าผู้ป่วยพร้อมก็สามารถพูดคุยแนวทางในระยะอันใกล้นี้ได้เลย ยังไม่ควรพูดเรื่องระยะยาว หรือพยากรณ์โรคในครั้งนี้ ควรพูดช้า ๆ พูดให้น้อย ๆ เฉพาะสิ่งที่จำเป็นใกล้ ๆ นี้เท่านั้น โดยสลับกับการสอบถามความเข้าใจเป็นระยะๆ (tell-ask-tell)

แพทย์ควรใช้ภาษาที่คนทั่วไปเข้าใจ (layman language) และควรฝึกใช้คำเรียกชื่อโรคต่าง ๆ ที่ไม่ชวนตระหนก เช่น หัวใจทำงานไม่ค่อยดี (แทนคำว่า หัวใจล้มเหลวหรือหัวใจวาย), ไตทำงานลดลง

(แทนคำว่า ไตวาย), น้ำคั่งค้างในปอด (แทนคำว่า น้ำท่วมปอด) เป็นต้น และแพทย์ควรหลีกเลี่ยงคำพูดเชิงลบให้มาก เช่น คำว่า แย่, แย่ลง, ทรมาน, เจ็บปวด, ทรมาน, ร้ายแรง, ลุกลาม, กระจาย, ระยะ 4 เป็นต้น

ก่อนจบการสนทนา ควรเปิดโอกาสให้ผู้ป่วยได้ซักถาม หลังจากนั้นแพทย์ควรพูดสรุป (summarize) สิ่งที่ได้พูดกันมาในวันนี้และนัดแนะการพบกันครั้งต่อไป เช่น

“คุณสมชายครับ หมอขอสรุปนะครับว่า วันนี้หมอได้แจ้งผลตรวจผลชิ้นเนื้อของคุณสมชาย สรุปว่าเป็นมะเร็งครับ แต่มีทางรักษาได้....โดยเราจะตรวจเอกซเรย์เพิ่มเติม และจะนัดมาให้ยาเคมีบำบัดในสัปดาห์หน้าครับ” เป็นต้น

### หลักการแจ้งข่าวร้ายในบางสถานการณ์จำเพาะ

หลักการแจ้งข่าวร้ายโดยเทคนิค “SPIKES” สามารถนำมาใช้ในการแจ้งข่าวร้ายเกือบทุกสถานการณ์ แต่ในบางสถานการณ์จำเพาะอาจมีหลักการบางอย่างเพิ่มเติม ได้แก่

#### ผู้ป่วยแยลงฉับพลันหรือเสียชีวิตโดยไม่ได้คาดหมาย

เนื่องจากเป็นข่าวร้ายที่ไม่ได้คาดหมายมาก่อน ทำให้ญาติ (หรือผู้ป่วย) ไม่ได้เตรียมใจมาก่อน บางครั้งจึงเกิดความระแวงไม่ได้ ดังนั้นหลักการคือ

1. แพทย์อาจต้องมีการแจ้งเป็นช่วง ๆ เป็นระยะ ๆ ว่าเกิดอะไรขึ้น ซึ่งแพทย์กำลังพยายามช่วยอยู่อย่างเต็มที่ แล้วจึงมาแจ้งอาการต่อมาเป็นระยะ ๆ จนท้ายที่สุดแจ้งว่าผู้ป่วยเป็นอย่างไร (แยลงเสียชีวิต เป็นต้น)

2. ควรอธิบายสิ่งที่เกิดขึ้นช้า ๆ อย่างละเอียด (อาจต้องบอกเวลาอย่างชัดเจนเป็นนาที ๆ ณ จุดต่าง ๆ) เพราะจะเป็นการทำให้ญาติเชื่อมั่นว่าแพทย์โปร่งใส ไม่ได้ปิดบังอะไรต่อญาติ อธิบายจนถึงตอนท้ายสุด แล้วจึงบอกข่าวร้าย

3. ควรอธิบายให้เห็นความพยายามของแพทย์ (และทีมแพทย์) ว่าไม่ได้นิ่งนอนใจ ได้พยายามแก้ไขสิ่งที่เกิดขึ้นอย่างเต็มความสามารถ แต่อย่าพูดปกป้องตนเองจนเกินไป

4. อย่าลังเลใจที่จะบอกญาติหรือผู้ป่วยว่า ท่านเสียใจกับสิ่งที่เกิดขึ้น

5. กรณีที่ท่านไม่ทราบสาเหตุที่เกิดขึ้น ไม่ควรด่วนแจ้งสมมติฐานของท่านหรือความเห็นของท่าน เพราะญาติมักจะถือว่าเป็นคำตอบที่แน่นอน ควรบอกว่ายังไม่ทราบแน่ชัด แต่จะรีบหวนหาอย่างละเอียดถี่ถ้วนที่สุดเพื่อหาสาเหตุจะดีกว่า

#### ผู้ป่วยเกิดภาวะแทรกซ้อน (ที่อาจพบได้ตามปกติ) จากการผ่าตัดหรือการผ่าตัด

มีหลักการคล้ายคลึงกันคือ

1. ควรอธิบายสิ่งที่เกิดขึ้นช้า ๆ อย่างละเอียดว่าขณะทำตอนนั้นเป็นอย่างไร เห็นอะไรที่สงสัยว่ามีภาวะแทรกซ้อนเกิดขึ้น จวบจนเราวินิจฉัยได้ว่าเกิดภาวะแทรกซ้อน

2. ควรแสดงให้เห็นความพยายามของแพทย์และทีม ว่าได้พยายามแก้ไขสิ่งที่เกิดขึ้นอย่างรวดเร็ว สุดความสามารถ และดีที่สุด

3. อย่าลังเลใจที่จะบอกญาติหรือผู้ป่วยว่า แม้สิ่งนี้จะเกิดขึ้นได้ (ดังที่ได้แจ้งตั้งแต่ก่อนทำหัตถการ) แต่ท่าน “เสียใจ” กับสิ่งที่เกิดขึ้น

#### ผู้ป่วยเกิดภาวะแทรกซ้อนจากความผิดพลาดของแพทย์

มีหลักการเหมือนกับผู้ป่วยที่เกิดภาวะแทรกซ้อนจากหัตถการ แต่ในกรณีนี้ไม่ต้องลังเลใจเลยว่า น่าจะบอกญาติหรือผู้ป่วยว่า “หมอขอโทษ” เพราะเกิดจากความผิดพลาดของเราจริง ๆ การขอโทษจากใจจริงมักทำให้ญาติหรือผู้ป่วยให้อภัยและไม่ติติงในที่สุด และมักช่วยลดการฟ้องร้องได้อย่างมาก

#### สรุป

การแจ้งข่าวร้ายเป็นกระบวนการที่สำคัญและมีประโยชน์ต่อผู้ป่วยเป็นอย่างยิ่ง การแจ้งข่าวร้ายเป็นทั้งศาสตร์และศิลป์ โดย “ศาสตร์” ได้แก่ การใช้เทคนิค “SPIKES” ส่วน “ศิลป์” ได้แก่ การไวต่อความรู้สึก ความเห็นอกเห็นใจ และการฝึกฝนจนชำนาญในที่สุด

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## เอกสารประกอบการอบรม



19 Oct2017





19 Oct 2017

หัวข้อ : Disclosure of medical errors negligence, and complications

## How to disclose Medical Errors

### Before disclosure

#### 1. Data gathering and prepare

เตรียมข้อมูลให้พร้อม อย่างครบถ้วน

#### 2. Preserve trust and relationship

อย่าทำลายความเชื่อใจและความสัมพันธ์

#### 3. Authority and leadership

อย่าฉายเดี่ยว ต้องทำงานเป็นทีม พร้อมผู้เกี่ยวข้อง

#### 4. Prompt disclosure

ทำเร็วที่สุด เมื่อทุกอย่างพร้อม

#### 5. Family involvement

ให้ทุกคนมีส่วนร่วมในการรับรู้ข้อมูล

#### 1. Focus on facts

อย่าเถา อย่ามั่ว อย่าแก้ตัวหรือคาดเดา

#### 2. Focus on patient's need

หาความต้องการให้เจอ อย่าทำให้สงสัยหรือมีคำถาม

#### 3. Reduce uncertainty

วางแผนการดูแลให้ชัดเจน ไม่มีใครชอบความไม่แน่นอน

#### 4. Sharpen your saw

ฝึกทักษะที่สำคัญ ฝึกฟัง ฝึกพูด ฝึกจับความรู้สึก ฝึกควบคุมอารมณ์

#### 5. Do responsibility

แสดงความเห็นใจ เสียใจ และรับผิดชอบ

#### 6. Show what you have learned

แสดงให้เห็นว่าการพัฒนาความปลอดภัยในการดูแลผู้ป่วย

#### 7. Careful documentation

ให้ความสำคัญกับเวชระเบียน

### When?

### After disclosure

#### 1. Offer follow up meeting

อย่าพยายามดำเนินการให้เสร็จสิ้นในครั้งเดียว แนะนำให้เจอกันบ่อย ๆ

#### 2. Offer/Refer to 2nd opinion

เปิดโอกาสให้มีทางเลือกที่ดีกว่าอย่ายื้อไว้หากหมดซึ่งศรัทธาหรือความไว้วางใจ

#### 3. Accept outcomes

ทำให้ดีที่สุด สุดท้ายต้องยอมรับผลลัพธ์ที่เกิดขึ้น

#### 4. Organization leadership

องค์กรต้องอย่าปล่อยให้บุคลากรเดียวตายหรือเผชิญหน้าโดยลำพัง



19 Oct 2017

หัวข้อ : Advanced care planning

BMJ



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Page 1 of 6

## CLINICAL REVIEW

### An introduction to advance care planning in practice

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Advance care planning has been defined as a process of formal decision making that aims to help patients establish decisions about future care that take effect when they lose capacity.<sup>1</sup> It recently gained increased importance in the United Kingdom, after being recommended by the end of life care strategy.<sup>2</sup> The first national guidance for health and social care staff in the UK was produced in 2007 and revised in 2011.<sup>3</sup> Before this, terms and concepts used in the UK had included "living wills" and "advance directives," which have been replaced by terminology outlined in the national guidance and the Mental Capacity Act 2005.<sup>4</sup>

Advance care planning differs from general care planning in that it is usually used in the context of progressive illness and anticipated deterioration. This has implications for its acceptability to patients. It is a voluntary process and may result in a written record of a patient's wishes, which can be referred to by carers and health professionals in the future. If a patient loses capacity, health and social care professionals should make use of information gleaned from the advance care planning process to guide them in decision making when needed.

The Royal College of Physicians and other national organisations stress the need to avoid a document driven or "tick box" approach to this process,<sup>5</sup> and many authors advise focusing on communication rather than on specific interventions or outcomes.<sup>6-8</sup> The success of advance care planning should therefore not be defined on the basis of completed paperwork alone.<sup>9</sup>

This review aims to provide an overview of the potential benefits and risks of advance care planning, to summarise barriers to taking part in it, and to give practical guidance to health professionals on how to approach the process, with reference to the Mental Capacity Act 2005. Although this article is based on UK law and practice, we believe that the concepts and approaches discussed could be applied more widely. For example, both the Australian and American Medical Associations endorse similar concepts to those used in the UK.<sup>10 11</sup>

#### What are the benefits of advance care planning?

Theoretically, the process can facilitate patient autonomy so that patients' future wishes can be carried out once they can no longer decide for themselves,<sup>1</sup> but evidence regarding real benefit is mixed. A controlled trial of the impact of combining improved communication about resuscitation preferences with information on prognosis found no improvement in the quality of end of life care.<sup>12</sup> Other authors have suggested that the wider advance care planning process may also be ineffective in achieving positive outcomes.<sup>13-16</sup>

Conversely, some evidence, including that from a recent small systematic review in patients with dementia and cognitive impairment,<sup>17</sup> points to several possible benefits. These include less aggressive medical care and better quality of life near death, decreased rates of hospital admission, especially of care home residents, and increased rates of hospice admission,<sup>18-20</sup> with those having completed an advance care plan being more likely to receive care that is aligned with their wishes.<sup>21 22</sup> A UK retrospective study of 969 deceased hospice patients found that those who had completed such a plan (57%) spent less time in hospital in their last year of life. It also found that those who died outside of hospital had a lower mean hospital treatment cost than those who died in hospital.<sup>23</sup>

Advance care planning is also thought to help families prepare for the death of a loved one, to resolve family conflict, and to help with bereavement.<sup>24 25</sup> For example, a randomised controlled trial of facilitated advance care planning versus usual care in elderly patients in Australia showed that 86% of patients in the intervention arm had their end of life wishes known and respected compared with 30% in the control arm. The same study highlighted a greater level of satisfaction among patients and relatives in the intervention group. Family members of patients in the intervention group who died had lower levels of psychological morbidity.<sup>25</sup>

A systematic review published in 2008 examined evidence for improving palliative care at the end of life. It included 41 articles relating to advance care planning and found moderate evidence supporting multicomponent interventions to increase patient

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**Summary points**

Advance care planning aims to help patients establish decisions about future care that take effect when they lose capacity

Evidence for the benefit of advance care planning is mixed; more recent evidence suggests that it can facilitate the delivery of care more in keeping with patient wishes and increase patient and family satisfaction with care

Advance care planning discussions should be centred around the beliefs, goals, and values of patients, rather than on specific outcomes or interventions

A sound working knowledge of the Mental Capacity Act 2005 is important when facilitating advance care plan discussions

**Sources and selection criteria**

We searched Medline, Embase, and the *Cochrane Database of Systematic Reviews* using the search terms "advance care planning" and "advance directives", focusing on publications in the past five years, but including older papers that seemed relevant. Where possible we prioritised systematic reviews and controlled trials. We did not carry out a systematic review of the literature and studies are of variable quality, with many being small.

uptake of advance directives; however, these studies seldom measured clinically important outcomes. The paper also concluded that recent research supports an approach to care planning that engages values, involves skilled facilitators, and focuses on key decision makers (for example, patients, care givers, and providers).<sup>26</sup>

Patients can find the process itself helpful, particularly when discussion focuses on their goals, values, and beliefs, rather than on particular treatments or interventions.<sup>25-28</sup>

Patients report several reasons for wishing to make advance decisions, including not wanting to be a burden on others and concern for self,<sup>27-29</sup> with underlying specific issues relating to their personal experiences and fears.<sup>29-30</sup>

**What are the risks and barriers to advance care planning?**

Some patients will not wish to engage in discussions about future care because this involves thinking about a deterioration in their condition.<sup>6-32</sup> There may also be cultural sensitivities to such conversations. Self identified barriers to the process in one qualitative study of older medical patients included perceiving advance care planning as irrelevant, having insufficient information to engage in the discussions, and the time constraints of health professionals.<sup>33</sup> A further challenge is that the process asks patients to predict their future experience of illness, which some may find difficult.<sup>34-35</sup> However, a person's willingness to engage in the conversation may change over time, so it may be appropriate to re-offer discussions at a later stage.

Equally, barriers may exist for professionals<sup>31-37</sup>; in particular, doctors may be unwilling to initiate such discussions, because this may "bring death into full view."<sup>36</sup> Some may fear that honesty about prognosis will cause patients undue distress or destroy their hope.<sup>6-38</sup> However, although caution in discussion is obviously needed, a longitudinal qualitative study found that patients have a variety of responses to, on the one hand, wanting support for hope and, on the other, wanting honest prognostic information; responses included being able to hope for things other than cure.<sup>38</sup> This accords with our experience—some degree of emotional upset may occur, but it is usually appropriate to the situation, and most patients who accept the offer of a discussion for advance care planning find such conversations empowering.

Some patients think that professionals should raise the matter,<sup>39</sup> so if we do not do this their needs may remain unmet. Being in a trusting relationship with patients,<sup>24</sup> or being able to develop such a relationship,<sup>40</sup> is helpful in this context.

**How can we initiate discussions?**

Advance care planning can apply to patients with a wide range of diagnoses, but particularly those with long term conditions or receiving end of life care.<sup>5</sup> It should be offered when the patient is still well enough to participate in the discussions and before any relevant loss of mental capacity.<sup>5-41</sup> This can mean that for certain conditions, such as dementia, discussions may have to be offered early in the course of disease. One UK systematic review found that a maximum of 36% of patients with cognitive impairment and dementia being admitted to a nursing home had capacity to participate in advance care planning.<sup>17</sup> However, data on the best timing of advance care planning discussions in patients with dementia are conflicting. One recent qualitative study suggested that patients with mild dementia find such discussions acceptable,<sup>42</sup> but another found that people with dementia had difficulty considering their future selves.<sup>35</sup>

More generally, some studies have identified particular triggers for initiating these conversations, such as recurrence of cancer.<sup>6</sup> The timing of conversations with patients with non-cancer conditions, such as chronic obstructive pulmonary disease, may also prove challenging. This disease is often not perceived to be terminal and therefore not relevant to the principles of advance care planning.<sup>36</sup> This reflects the nature of chronic conditions in which disease can be stable and well managed for many years, before moving on to the terminal phase. However, because sudden changes in condition can occur, the opportunity to take part in advance care planning could be missed if the subject is not broached early on.

Another crucial factor is the communication skills of health professionals. A number of authors recognise the potentially challenging, sensitive, and complex nature of conversations about advance care planning,<sup>13-43</sup> with others recommending that practitioners need specific training.<sup>5-44</sup> One component of such highly skilled communication is knowing when not to proceed with discussions—for example, when doing so might cause disproportionate levels of distress<sup>5</sup>—and how to "titrate" information over time.

Box 1 includes a list of suggested triggers for initiating or reviewing such discussions.

**Practical approaches to communication**

When preparing to offer discussions it may be useful to consider the following:

- Patients may need time to think and reflect, so the initial advance care planning process may extend over several conversations.<sup>5-6</sup> One study found that the process took a median of 60 minutes over one to three conversations<sup>25</sup>

**Box 1 Triggers for initiating or reviewing advance care planning discussions**

There is no agreed standard frequency with which to review these discussions, so the interval should be based on patients' wishes, taking into account their clinical condition.

Triggers include:

- Patient initiates the conversation
- Diagnosis of a progressive life limiting illness
- The diagnosis of a condition with a predictable trajectory, which is likely to result in a loss of capacity, such as dementia or motor neurone disease
- A change or deterioration in condition
- Change in a patient's personal circumstances, such as moving into a care home or loss of a family member
- Routine clinical review of the patient, such as clinic appointments or home visits
- When the previously agreed review interval elapses

- Ensure that any outcomes of these discussions are appropriately shared among relevant teams and organisations,<sup>26 45</sup> and updated if decisions change
- Avoid giving the impression that it is possible to anticipate and plan for every eventuality<sup>13</sup>
- Do not assume that other health or social care professionals have offered opportunities for such discussions<sup>36 37</sup>
- Discussions that take place in the patient's wider family or social network may give rise to conflict, which is best dealt with early, to avoid conflict coming to light when the patient has lost capacity or died.<sup>24</sup>

Mahon suggests two questions that may be useful for initiating an advance care planning discussion that focuses on the patient's goals:

- 1) If you cannot, or choose not to, participate in healthcare decisions with whom should we speak?
- 2) If you cannot, or choose not to, participate in decision making what should we consider when making decisions about your care?<sup>8</sup>

For some patients answering question 1 may be as far as they wish to take such a discussion, and hopefully this question can be asked without causing patients undue anxiety. Box 2 outlines our communication suggestions.

## How does advance care planning fit with the Mental Capacity Act 2005?

As well as knowing about a patient's disease and its likely consequences,<sup>5</sup> an adequate understanding of the law (including capacity assessment), the advance care planning process, and the related documentation is necessary.<sup>9 48</sup> However, two UK studies have shown that some professionals have a limited understanding of advance care planning,<sup>44 49</sup> with the authors of one suggesting that those with specialist skills in particular diseases may be better placed to undertake more complex aspects of the process.<sup>44</sup> This section serves as a brief introduction to some of the key legal problems.

The Mental Capacity Act 2005 legislates for England and Wales on the way in which decisions are made by, and on behalf of, people with impaired mental capacity.<sup>4</sup> It sets out five principles and a legal framework designed to protect patients with impaired capacity and their carers, who have to make decisions about their care and treatment. It is accompanied by the Mental Capacity Act 2005 code of practice, and practitioners have a legal duty to have regard to this.<sup>50</sup> Abiding by a person's wishes about a health related advance decision comes into effect only once the person has lost capacity to make that particular decision.

## Mental capacity

People are assumed to have capacity unless it is established that they lack capacity despite all practicable steps taken to help them make the decision in question (see box 3 for the mental capacity assessment).

## Best interests

Section 4 of the act deals with making decisions in accordance with the best interests of the person lacking capacity and specifies an initial checklist of common factors that must always be considered. It states that whoever determines what is in someone's best interests must consider, so far as is reasonably ascertainable, the person's past and present wishes and feelings, particularly any relevant written statement made when he or she had capacity,<sup>4</sup> thus giving "weight" to the advance care planning process.

## What are the potential outcomes of an advance care planning discussion?

In addition to documents recording a person's preferred place of care or death, advance care planning has three main tools—advance statements, advance decisions to refuse treatment, and lasting powers of attorney.

## Advance statements

These are statements about what the patient would or would not want to happen in the future, their goals of care, or their personal values; they are sometimes known as a statement of preferences and wishes. They can be about medical treatment ("I would wish to be ventilated if I stop breathing") or about social aspects of care ("I prefer coffee in the morning"). They are not legally binding but must be taken into account when best interest decisions are made about the person after capacity has been lost. They can be written by the patient or be verbal statements. It is useful to record verbal statements in the patient record, and it is important that they are accessible for those making decisions in the future.

## Advance decision to refuse treatment

Valid and applicable advance decisions to refuse treatment (box 4) are legally binding statements (usually written documents) that allow patients to refuse specific medical treatments if they lose capacity in the future. Patients can refuse only medical and nursing treatments in advance and not basic care (such as the offer of food and drink by mouth and repositioning in bed).

It is best, but not a requirement, if the specific circumstances in which patients wish to refuse treatments are made clear, because this information will be used by clinicians in the future

**Box 2 Communication tips***Initiating the conversation*

Start with general open questions, then be guided by the patient's cues and responses to know whether to explore further

Examples:

- How have you been coping with your illness recently?
- Do you like to think about or plan for the future?
- When you think of the future, what do you hope for?<sup>46</sup>
- When you think about the future, what worries you the most?<sup>46</sup>
- Have you given any thought to what kinds of treatment you would want (and not want) if you became unable to speak for yourself?<sup>47</sup>
- What do you consider your quality of life to be like now?<sup>47</sup>

*During the conversation*

Use language that patients can understand and any other communication aids you might need

Give patients enough information to make informed choices without overloading them

Clarify any ambiguous statements that patients make—for example:

- Patient: "I don't want heroics"
- Professional: "What do you mean by heroics?"

*Ending the conversation*

Summarise what has been discussed to check mutual understanding, or ask the patient to do so

Screen for any other problems—for example: "Is there anything else you would like to discuss?"

Arrange another time to continue, complete, or review the discussion if necessary—for example, if the patient would like help completing an advance decision to refuse treatment

Document the contents of the discussion in the patient record

Share the contents (with the patient's permission) with anyone else who needs to know, such as family, carers, the community team, and the general practitioner or specialists

**Box 3 Assessing mental capacity**

Mental capacity is decision specific and time specific—it is specific to the decision in question and may be of time limited relevance.

The test for mental capacity has two parts:

- The diagnostic test. This is positive if the person has "an impairment of, or disturbance in the functioning of, the mind or brain" (Mental Capacity Act 2005 section 2). Otherwise, by definition, the person has capacity
- The functional test (Mental Capacity Act 2005 section 3) applies only if the diagnostic test is positive. People who can understand, retain, and use or weigh information relating to a decision, as well as be able to communicate their decision, have not lost capacity, even if the diagnostic test is positive. Loss of one or more of these four elements confirms loss of capacity for the specific decision

Mental capacity for a particular decision may fluctuate over time and may need to be reviewed frequently. For example, a patient may be temporarily incapacitated by an episode of sepsis, or through the use of alcohol.

**Box 4 Determining whether an advance decision to refuse treatment is valid and applicable**

Such decisions come into effect only if the person has lost mental capacity to make the decision in question. The person must have had relevant capacity at the time the advance decision was made and it must be about the decision in question.

*Validity*

For such a decision to be valid, it should not have been withdrawn by the person, and the person should not have later behaved in a way that is inconsistent with it. In addition, if the person has subsequently made a lasting power of attorney regarding the same decision the advance decision is rendered invalid.

*Applicability*

For the refusal to be applicable it must be about the treatment currently in question and relate to the circumstances in which the patient now finds himself or herself, if these have also been specified. For example, a person specifically refusing antibiotics for treatment of a chest infection might receive antibiotics for a urinary tract infection if clinically appropriate. However, if the advance decision covers all antibiotics under the specified circumstances then health professionals would be bound not to administer them.

An advance decision may not be applicable if circumstances have changed (for example, an unanticipated advance in medical treatment) and there are reasonable grounds to believe that these changes would have affected the advance decision if the person had known about them when making the decision.

*Life sustaining treatment*

When the treatment to be refused is potentially life sustaining, such as cardiopulmonary resuscitation, as well as being valid and applicable, the decision must be written, signed by the patient in the presence of a signed witness, and must state that it applies even if life is at risk.

to determine if the refusal is applicable. The wording of these statements can be difficult, because potential future situations must be anticipated and described unambiguously. If more than one circumstance is specified for a given refusal of treatment, all have to be present at the same time for the advance decision to apply. Verbal wishes to refuse treatments that do not sustain life can be recorded in the patient's notes.

If you are satisfied that the advance decision to refuse treatment is valid and applicable then you will have to abide by it (best interests do not apply). The only circumstance in which an advance decision is not binding is when the person is detained under the Mental Health Act 1983.<sup>51</sup> Such patients can be treated for their mental disorder without their consent, even if they have a valid and applicable advance decision to refuse the treatment

in question (electroconvulsive therapy is an exception to this rule).

### Lasting power of attorney

These are legal documents that replace the previous enduring power of attorney. They allow patients (donors) to nominate someone (attorney) to whom they want to give decision making powers (if they lose capacity in the future). There are two types of lasting power of attorney: "property and financial affairs" and "health and welfare." Once made, these documents must be registered with the Office of the Public Guardian (for a fee) before coming into effect. It is possible to nominate more than one person as an attorney, or nominate different people for different decisions.

A health and welfare lasting power of attorney comes into effect only when the donor loses the capacity to make the decisions that are covered by the document. If there are worries that an attorney is not making decisions in the best interests of the donor, the decision should be challenged. It can then be adjudicated on by the Court of Protection (which might appoint a court appointed deputy, usually someone close to the patient, who would be able to take best interests decisions for the patient).

### What are electronic palliative care coordination systems?

Appropriate dissemination of advance care planning decisions is a challenge; other than for lasting powers of attorney, the UK has no central register of advance care plans. Electronic palliative care coordination systems are designed to improve communication and facilitate health professionals' access to this information. Electronic registers, or urgent care records, such as Coordinate my Care in London ([www.coordinatemycare.co.uk/index.html](http://www.coordinatemycare.co.uk/index.html)), hold immediately accessible information about patients' advance care plans and other information, such as treatment escalation plans, and are available to a wide range of relevant professionals. In some areas, this has led to an increase in patients dying in their preferred place of care.<sup>52</sup>

### When should advance care planning decisions be reviewed? (see box 1)

Although no specific evidence or recommendations are available on when to review these decisions, on the basis of personal experience, several factors may be relevant and should prompt review. For example, if the personal circumstances of patients change, such as place of residence or perception of quality of life, they may wish to reconsider their decisions. New therapeutic options may become available or, as the condition progresses, the patient's values and goals may change, and this may affect earlier decisions. Advance care planning must be reconsidered regularly, either to confirm or amend the content, while the person has mental capacity to do so. This will allow the document to reflect the patient's current wishes and increase the likelihood that it will be judged as valid and applicable at the relevant time.

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**Additional educational resources***Resources for patients*

National End of Life Care Programme ([www.endoflifecare.nhs.uk/search-resources/resources-search/publications/planning-for-your-future-care.aspx](http://www.endoflifecare.nhs.uk/search-resources/resources-search/publications/planning-for-your-future-care.aspx))—Outlines the different options available to people when planning for their end of life care and comes in a range of languages

Aging with Dignity ([www.agingwithdignity.org/forms/5wishes.pdf](http://www.agingwithdignity.org/forms/5wishes.pdf))—US based website that aims to help people take control of how they are treated if they are seriously ill

Regents of the University of California ([www.prepareforyourcare.org](http://www.prepareforyourcare.org))—Aims to help patients make medical decisions for themselves and get the right medical care

*Resources for professionals*

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# Advance Care Planning

Linda L. Emanuel, MD, PhD; Charles F. von Gunten, MD, PhD; Frank D. Ferris, MD

**A**dvance care planning is the process of planning for future medical care, particularly for the event when the patient is unable to make his or her own decisions. It should be a routine part of standard medical care and, when possible, conducted with the proxy decision maker present. It is helpful to think of the process as a stepwise approach. The steps include the appropriate introduction of the topic, structured discussions covering potential scenarios, documentation of preferences, periodic review and update of the directives, and application of the wishes when needed. The steps can be integrated flexibly into routine clinical encounters by the physician and other members of the health care team. The process fosters personal resolution for the patient, preparedness for the proxy, and effective teamwork for the professionals. The process also has pitfalls of which to be aware.

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## WHAT IS ADVANCE CARE PLANNING?

Advance care planning is a process, not an event. It is the process of planning for future medical care in the event that the patient is unable to make his or her own decisions. During this process, patients explore, discuss, articulate, and document their preferences.<sup>1</sup>

The process helps patients identify and clarify their personal values and goals about health and medical treatment. They identify the care they would like, or not like, to receive in various situations. Patients also determine whom they would like to make health care decisions on their behalf in the event they cannot do so themselves.<sup>2</sup>

Ideally, advance care planning is a process of structured discussion and docu-

mentation woven into the regular process of health care that is reviewed and updated on a regular basis.<sup>3</sup> It is designed to ensure that a patient's wishes will be respected in the event that the patient is unable to participate in decision making.<sup>4,5</sup> In the case of a child, it is designed to ensure that the patient's parents are provided with an understandable discussion of the child's prognosis and of the treatment options, should the child's condition deteriorate to a terminal state.<sup>6</sup> The sense of control and peace of mind that this process fosters in the patient and the reduction of anxiety in proxy decision makers are important benefits.

Advance care planning is important for physicians for many reasons. Patients have a right to participate in the planning of their health care. Physicians have a legal and professional responsibility to ensure this, even if the patient loses the capacity to make decisions. The process of determining those preferences for treatment builds trust and a sense of teamwork among the patient, proxy, and physician in several ways. The invitation to

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discuss future care permits the patient (or the parents if the patient is a child) to understand his or her own values, goals, and preferences that govern his or her life. The physician and proxy learn about those preferences and needs. The process helps to relieve anxieties and fears on both sides because a spirit of frankness and openness is fostered. Advance care planning is preventive medicine because it avoids future confusion and conflict.

The model for advance care planning can be applied to other decision-making processes as patients plan for the end of their lives (eg, planning for bequests, autopsy, burial or cremation, funeral or memorial services, and guardianship and choices of caregivers and settings for care).

### INVOLVEMENT OF OTHERS

The physician plays an important role in initiating and guiding advance care planning. The physician needs to be involved in some, but not all, stages of advance care planning to understand the patient and establish a trustworthy shared decision-making process. Recent studies suggest that patients prefer discussing these issues with their family members. However, as the physician will be responsible for the actual medical orders, sufficient involvement is necessary for the physician to feel comfortable and able to pursue the goals and priorities for care that the patient wants.

Many physicians are concerned that advance care planning is too idealistic or time intensive to include it in their busy practice.

This article provides a framework for the routine and practical inclusion of the process into practice. The patient, proxy, and family can perform most of the work without the physician if they are given a worksheet and background materials. For purposes of reimbursement, the time that the physician takes to counsel and provide information about ad-

vance care planning can be incorporated into the coding of complexity of the encounter.

Some physicians choose to have other members of the health care team assist them with advance care planning (eg, a nurse, physician assistant, or social worker). Once the patient's ideas have been gathered, the physician can focus on the core discussions in direct meetings with the patient, proxy, and family. Preparatory work will permit these discussions to be to the point and effective. Once the core discussion has taken place, the patient should be invited to reflect on things and to return at a subsequent visit with decisions to review.

There are legitimate cultural, ethnic, and age-related differences in approaches to medical decision making and advance care planning. However, generalizations should not be used to rationalize the omission of this topic for an individual patient. Pediatric patients and their parents can benefit from the advance care planning process, too. Determine how a patient and family want medical information to be shared and medical decision making to be handled early in the therapeutic relationship.

Terms used in advance care planning can be confusing. *Advance directives* are previous directives by the patient for his or her own health care. Advance directives fall into 2 categories, those concerning instructions for medical care and those concerning designation of a proxy for the patient. *Instructional directives* for care can be recorded in a number of types of documents. A *living will* is usually a simple statement asking for no heroic care in case of poor prognosis. A personal letter may also be used. A *values history* is a statement of values regarding health care in life-threatening illness situations. A *medical directive* is a set of instructions based on likely scenarios of illness, goals for care, and specific treatments, combined

with a general values statement. It is also combined with a proxy designation section. A person who is empowered to make decisions in the place of the patient is sometimes termed a *health care proxy* or a durable power of attorney for health care.

### FIVE STEPS FOR SUCCESSFUL ADVANCE CARE PLANNING

#### Step 1: Introduce the Topic

Research shows that most patients believe that it is the physician's responsibility to start advance care planning and will wait for the physician's initiative. Advance care planning is most easily accomplished during stable health, since changes often require a period for adjustment before the patient will have stable goals again.

In the face of life-threatening illness or other significant change in health status, advance care planning becomes even more necessary. Try to find a time when there is as much stability and adjustment to the new illness circumstances as possible.

Sometimes the most difficult part of the advance care planning process is the introduction of the topic. Physicians often have a number of concerns that make them reluctant to do so. Some may be concerned that the subject of advance care planning will frighten the patient or send the wrong message. Others may be uncertain about the most effective approach to use. In fact, most patients welcome the opportunity to discuss their preferences with their physician, and physicians who routinely engage in the process find it helpful and not too time-consuming.

Although some patients will be more likely to need advance care planning than others, healthy people who experience an unexpected illness, such as major trauma, can suddenly be the patients most in need

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of advance directives. Whenever possible, physicians routinely should initiate the advance care planning process with every adult patient in their practice, regardless of age or current state of health. An outpatient office visit or other nonthreatening setting is ideal.

For children with a chronic illness, the optimal timing of advance care planning will vary. At a minimum, the discussion should take place after a relapse of disease, or at the time of significant complications, but before the child is in a state of crisis.

When introducing the topic, inquire how familiar the patient is with advance care planning. Some patients may already have advance directives in the form of a living will or durable power of attorney for health care. If this is the case, review the documents and amend them if appropriate. An advisory medical directive can be used to amend existing statutory documents.

Before beginning the process, be prepared to explain the purpose and nature of the process that you recommend using. You may have literature that you would like the patient to read. If you are using a validated worksheet, give it to the patient to look over before the next discussion. Explain the roles of other family members or a proxy. If appropriate, introduce other members of the health care team who will be involved in the process.

Although most patients will welcome the opportunity to discuss these matters, be aware of the patient's comfort level during the introduction of the topic. If a patient (or parent if the patient is a child) does not seem comfortable talking with you, be supportive and provide information, but do not force the conversation. It may happen later when the patient is ready.

As patients frequently wish to minimize the decision-making burden for family, suggest that the pa-

tient involve family members, friends, and even members of the community to explore how best to manage potential burdens. Ask the patient to identify a possible proxy decision maker, who might act on his or her behalf, to be involved in subsequent conversations. The best proxy decision maker is not always a family member. Sometimes the decisions are too difficult for people close to the patient, who may be overly influenced by their attachment or by burdens of care. Whether close or not so close, the proxy should be someone whom the patient trusts and who would be willing and able to represent the patient's wishes. Encourage the patient to bring that person, or persons, to the next meeting and book a time to follow up.

### Step 2: Engage in Structured Discussions

A critical success factor for advance care planning is the ability to structure discussions with the patient that convey the information patients need and to elicit relevant preferences to determine their advance directives. To prevent any misunderstanding, remind the patient that it is the goal of advance care planning to plan for the potential loss of his or her capacity to make decisions, temporarily or permanently. Convey commitment to follow the patient's wishes and to protect the patient from unwanted treatment or undertreatment, and convey intent to help plan for any caretaking needs of the patient's family.

**Role of the Proxy.** Involve the potential proxy decision maker in the discussions and planning so that he or she can have a thorough and explicit understanding of the patient's wishes. Usually, the appropriate role for the proxy during the initial discussions is to listen, perhaps to take notes, and to ask questions for clarification. A joint meeting involving the

patient, physician, and proxy to ensure common understanding can be invaluable if the proxy and physician are later called on to collaborate in decision making.

As part of the advance care planning process, the patient should specify the role he or she would like the proxy to assume if the patient is incapacitated. Proxies may try to implement specific treatment choices, they may try to decide according to the patient's best interests, or they may decide by taking into consideration the interests of all parties that the patient cares about in a form of substituted judgment. Although these possibilities often coincide, they may not, and it can be very helpful for the patient to decide which standard is most important.

In all cases, the proxy will need to work with the physician and, in general, should have the same participation in decisions that the patient would have had. Most commonly, the proxy uses a blend of standards—his or her own judgment based on the situation and what he or she knows about the patient's wishes. This allows for unexpected factors that could not be anticipated during the advance care planning process.

**Patient and Proxy Education.** At the core of advance care planning is the empowerment and preparedness of the patient and proxy. Both usually require some education, time for reflection, and discussion. To make informed choices, the patient must understand the meaning of the various clinical scenarios under discussion, as well as the benefits and drawbacks of the various treatment options. The discussion should provide insight into the types of clinical scenarios that might arise and the types of decisions that proxies most commonly face.

Define key medical terms using words the patient and proxy can understand. Explain the benefits and burdens of various treatment op-

tions (eg, life support on a ventilator may be needed for a short time only if the underlying problem is reversible). Remind them that any intervention can be refused or stopped if it is not meeting overall treatment goals. Because recovery cannot always be predicted, help patients to consider situations involving uncertainty, incomplete recovery, or even death.

**Elicit the Patient's Values and Goals.** Develop an understanding of the patient's values and goals related to health and illness. For pediatric patients, involve them to the level at which they are comfortable and work with the parents or guardians. There are a number of ways to facilitate this part of the discussion. Ask about past experiences—the patient's own or those of other people the patient knows. Describe possible scenarios and ask the patient what he or she would want in such a situation.

As a range of clinical situations is reviewed with the patient, it will be possible to get a sense of where thresholds exist for withdrawal or withholding of care. Help the patient to articulate his or her own general principles, values, and goals for care in given situations and specific treatment wishes. Consider asking the patient if he or she wants to write down in a letter to the physician how such things should be handled.

**Use a Validated Advisory Document.** To guide the discussion and capture patient preferences, consider using a worksheet or other carefully developed and studied tool. Many people find that, by using a worksheet, the discussion with the patient readily identifies the patient's values and attitudes regarding health and medical care across a range of medical situations, possible goals, and treatment choices. By going through various scenarios and options, the patient's personal

threshold for use or nonuse of interventions can become clearer. Proxy decision makers can be identified and their roles defined.

Ensure that the worksheet includes a range of potential scenarios that patients should consider. It should elicit the patient's values and goals related to health and medical care in general terms and should include the most common lifesaving interventions. If a patient already has a life-threatening condition, the conversation may be more focused on specific scenarios and treatment issues. For example, a patient with end-stage cardiomyopathy needs to consider the issues of cardiopulmonary resuscitation and the role of intensive care units. The patient with end-stage renal disease must consider dialysis. The patient with advanced acquired immunodeficiency syndrome needs to consider dementia and respiratory failure.

A number of validated worksheets are available from which to choose.<sup>7-9</sup> They provide a consistent approach, are easy to use, and reduce the chance that important information will be left out or framed in a biased way; the preferences they elicit tend to be reliable and durable reflections of the patient's wishes. Once they are complete, worksheets can serve as a resource that the patient, proxy, and family members take home. They may also be able to serve as a formal advisory document.

### Step 3: Document Patient Preferences

**Formalize the Directives.** Once the patient has made some decisions, to avoid the possibility of a directive that cannot be implemented, it is crucial for the physician to review the advance directives with the patient and proxy. Check for, and help to correct, any inconsistencies and misunderstandings. Make sure that the directives provide the type of in-

formation needed to make clinical decisions.

After a final review is complete, ask the patient to confirm his or her wishes by signing the directives. Although any statement of a patient's wishes—written or verbal—can be considered an advance directive and should be respected by physicians, a formal written document signed by the patient can avoid ambiguity.

**Enter Directives Into the Medical Record.** Once the directives have been reviewed and accepted, the physician must document them formally in the patient's medical record. When a validated worksheet has been used to structure the planning discussion, the completed, finalized, and signed worksheet can itself be used as the entry in the medical record.

In the absence of a validated worksheet, the physician should describe the patient's wishes in a written document and ask the patient to review and amend it as appropriate. Once everyone is satisfied, have the patient sign the document and enter it into the medical record. It is also useful for the physician and proxy to sign the advance directive and provide their location information. This offers reassurance to the patient and helps to ensure the physician's and proxy's involvement in eventual decision making.

**Recommended Statutory Documents.** For added protection, patients should be encouraged to complete one or more statutory documents (eg, living will or durable power of attorney for health care) that comply with state statutes. Physicians should familiarize themselves with the specific advance directive statutory requirements of their state. They can do this by checking with their hospital's legal counsel, their state attorney general's office, or their local medical society.

**Distribute the Directives.** It is important to have these records wherever the patient may receive care. Place them into a central repository, such as a hospital or a regional or national center. Provide copies to the patient, proxy decision maker, family members, and all health care providers as appropriate. Use wallet cards to help ensure that information is available when it is needed.

**Include Advance Directives in the Plan of Care.** Once preferences have been established, the physician may need to change the plan of care and put certain things in place to ensure that the patient's wishes can be followed. For patients who may wish to remain at home and never be taken to an emergency department or hospitalized again, appropriate alternative arrangements, including referral to a home hospice agency, provision of appropriate medications, and instructions detailing how to handle symptoms and crises, may be needed. Practical suggestions may be helpful. Consider posting telephone numbers by the home telephone to call in an emergency (eg, the hospice nurse on call) or numbers not to call (eg, 911).

#### Step 4: Review and Update the Directive

It is important to revisit the subject of advance care planning on a periodic basis to review the patient's preferences and to update the documents. Major life events, such as illness, marriage, the birth of a child, or the death of a loved one, may affect a person's attitude toward his or her health care and/or end-of-life care.

Any changes in preferences warrant discussion to allow the patient to reassess and to ensure that the physician and proxy decision maker fully understand the new wishes. Changes in preferences should be documented, and existing documents should be updated and shared appropriately.

#### Step 5: Apply Directives to Actual Circumstances

When patients become incapacitated, the application of previous wishes to real circumstances can be challenging. The following guidelines may be helpful to ensure that a patient's advance directives are followed as closely as possible.

Most advance directives go into effect when the patient is no longer able to direct his or her own medical care. Learn to recognize when a patient becomes incapable of making decisions. Although situations where the patient is unresponsive are obvious, if the patient has some ability to respond, the physician first must determine the patient's capacity to make decisions.

Never assume an advance directive's content without actually reading the document. Do not take for granted that patients who have living wills want treatment withheld. Some people indicate within their living will that they want all measures taken to prolong their life.

Advance directives should be interpreted in view of the clinical facts of the case. Validated documents are likely to be more useful than short statements or statutory documents. No matter how thorough they are, advance directives cannot anticipate all possible circumstances. The proxy and the physician may need to extrapolate from the scenarios described in the advance directive to the current situation, and to make an educated guess as to what the patient would want if he or she were able to speak for himself or herself.

Whenever significant interpretation is necessary, the physician should consult the patient's proxy. Sometimes the physician and/or proxy may believe that a patient would have indeed wanted something other than what is reflected by a strict reading of the advance directive. In this case, they should work together to reach consensus.

Certain patterns of decisions have high predictability and follow logic. For instance, a decline of less invasive interventions has been shown to predict decline of more invasive interventions. Acceptance of more invasive interventions predicts acceptance of less invasive interventions. If a patient has indicated that he or she would like intervention in a poor-prognosis scenario, there is a high probability that the patient would also accept intervention in a better-prognosis situation. Likewise, if the patient has indicated that he or she would decline intervention in a better-prognosis scenario, there is a high probability that he or she would also decline if the prognosis were poor.

If disagreements cannot be resolved, assistance should be sought from an ethics consultant or committee.

#### COMMON PITFALLS OF ADVANCE CARE PLANNING

Anticipating and avoiding the common pitfalls is essential to a successful advance care planning process. There are several.

##### Failure to Plan

Do not avoid advance care planning. Too often, situations occur and decisions are made without the benefit of advance care planning. Be proactive. It is easy to forget the central role of the patient, and easy to forget the importance of the proxy. Involve both early and often.

##### Proxy Not Present for Discussions

Do not leave the proxy decision maker(s) out of the initial discussions with the patient.

##### Unclear Patient Preferences

Vague statements can be dangerously misleading. Clarify patient

preferences if they do not seem clear to you or to the proxy. For instance, patients who make statements such as "I never want to be kept alive on a machine" should be asked to clarify whether their wishes would change if their condition were readily reversible, or if their prognosis were unclear.

#### Discussion Focused Too Narrowly

Avoid isolated do-not-resuscitate discussions; they often create chaotic emotions and thoughts in patients who have to imagine imminent death to make the decision. A do-not-resuscitate discussion is usually an indication that other palliative goals and measures should be considered in the context of a range of scenarios.

#### Communicative Patients Ignored

Sometimes people assume that what a patient wants in the present is what he or she indicated for future possible scenarios. As long as the patient is competent, talk to him or her. An impaired patient may still be able to express wishes at some level. In such cases, the advance directive and tangible evidence of the patient's current wishes should be taken into account.

#### Advance Directives Not Read

Sometimes physicians assume that they know what is stated in an advance directive. This is a mistake. Advance directives can be for aggressive intervention, comfort care, or a wide range of specific views and must be read and understood.

#### COMPLEMENTARY APPLICATION OF THE MODEL FOR ADVANCE CARE PLANNING TO PREPARE FOR LAST HOURS OF LIFE

Planning other issues that face patients at the end of their lives is critical if their needs and expectations are to be respected by health care

professionals and family members who will survive them. Although it would be ideal if all patients and families prepared for death well in advance of the final hours of their lives, most patients with advanced illnesses and their families have not discussed or prepared for their death.

As patients approach the last hours of their lives, they have a last chance to finish their business, create final memories, give final gifts, and say their good-byes. If appropriately assisted, considerable planning can be accomplished around many of these issues.

The 5-step model for eliciting, documenting, and following advance directives can be used to guide these decision-making processes and to document patient choices. As these important tasks are generally more than individual physicians can handle, other members of the interdisciplinary team can help patients and families complete their business and get their affairs in order.

In preparing for death, it is important to understand the perspective and wishes of all who are present, ie, the patient, the family, and the caregivers. Personal expectations, agendas, fears and phobias and acceptable setting(s) for care need to be clear, since any one person may alter the course of care unexpectedly and may interfere with the patient's wishes if such are not clearly known. Personal, cultural, and religious values, beliefs, and practices need to be anticipated and respected, as missed rites or rituals or errors made by unknowing caregivers may have grievous consequences in the eyes of the patient or family members. Identification and acknowledgment that some family members have a need to give care and others do not will help to allow each to participate as closely as makes him or her comfortable.

#### Advance Practical Planning

Many patients will choose to get their financial and legal affairs in or-

der, give gifts, and plan for bequests, organ donation, autopsy, burial or cremation, their funeral or memorial services, and guardianship of their children as they finish their business. Some patients will even want to give family members permission to build new lives after they die.

#### Choice of Caregivers

The choice of caregivers for each patient is crucial as vulnerability increases. Patients may or may not want family members to care for them. Family members may or may not be able to assume responsibilities for caring and ideally should have the opportunity to be family first, and caregivers only if they and the patient agree to the role. All caregivers need to have the opportunity to change their role if they feel the stress is too much, or if they are not getting enough of a chance to finish their personal business with the patient.

#### Choice of Setting

The choice of care setting for the last hours of the patient's life should be as acceptable as possible to the patient, the family, and all caregivers. Each setting will carry benefits and burdens. Whatever the choice, the setting should permit family members to remain with the patient as much as they want, and should provide them with opportunities for privacy and intimacy. Although dying at home may be the wish of many patients, such a choice may expose family members to undue burden or compromise their careers, personal economic resources, or health. If the number of able caregivers and personal resources is limited, or if family members are afraid of ghosts and would not be able to live on in their home afterward, care and death in the home may not be the best choice. An alternate inpatient setting may be a hospice or palliative care facility,

a skilled nursing facility, or even an acute care facility. Depending on the resources that are locally available and whether the staff is skilled in this kind of care, these alternative settings may lead to a far better outcome.

### SUMMARY

Advance care planning should be a routine part of standard medical care that is integrated into clinical encounters by the physician and other members of the health care team. Formally, it can be thought of as a stepwise approach, to include the appropriate introduction of the topic, structured discussions covering potential scenarios, documentation of preferences, periodic review and update of the directives, and application of the patient's wishes when needed. Less formally, the process fosters personal resolution for the patient, preparedness for the proxy, and effective teamwork for the professionals.

A number of critical factors contribute to a successful process and outcome: physician guidance and participation, family or proxy participation, and use of a worksheet or structured materials to foster discussion and documentation.

The process also has pitfalls of which to be aware. Vague or misleading statements of wishes can be hazardous; failure to involve the proxy risks discord around decisions; premature activation of the di-

rective when the patient is still competent fails to honor the patient's real-time autonomy; and assumption about wishes in advance directives being for nonintervention may not be accurate.

The following are the key points:

- Every person has the right to participate in the planning of his or her health care.
- Consider using a validated worksheet to guide discussions. Patients, families, and proxies can complete them at home after they have been introduced.
- Revisit the subject of advance care planning on a periodic basis, particularly with major life or health changes.
- Do not presume that patients who are very ill lack the ability to make decisions.

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19 Oct 2017

หัวข้อ : communication with relatives with bereavement

### Communication with relatives with bereavement

#### สถานการณ์

- คุณวิมลอายุ 65 ปี ป่วยเป็นโรคมะเร็งลำไส้ใหญ่มานาน 1 ปี เคยได้รับการผ่าตัดและให้ยาเคมีบำบัดแต่อาการไม่ดีขึ้น
- ครั้งนี้มานอนโรงพยาบาลด้วยอาการแน่นท้อง คลื่นไส้ อาเจียน เนื่องจากมะเร็งอุดตันลำไส้ และมะเร็งมีการกระจายไปยังตับและปอด
- แพทย์ได้แจ้งให้ญาติทราบว่าโรคดำเนินมาจนถึงระยะสุดท้ายแล้ว เบื้องต้นญาติยอมรับ
- ผู้ป่วยอยู่โรงพยาบาลได้นาน 1 สัปดาห์จึงเสียชีวิต

#### สถานการณ์

- คุณสมหญิงอายุ 35 ปี เป็นลูกสาวของคุณวิมล
- คุณสมหญิงอยู่เฝ้าดูแลมารดาตลอดในช่วงที่อยู่ที่โรงพยาบาลครั้งนี้
- เมื่อมารดาเสียชีวิตคุณสมหญิงยังทำใจไม่ได้ ร้องไห้เสียใจเป็นอย่างมาก แพทย์จึงเชิญคุณสมหญิงมานั่งคุยกัน

#### สถานการณ์

- คุณสมหญิง มีอาชีพรับราชการครู
- ปัจจุบันอาศัยอยู่กับสามี มีบุตรด้วยกัน 1 คน อายุ 3 ขวบ
- มีพี่น้องทั้งหมด 3 คน คุณสมหญิงเป็นบุตรคนโต น้องอีก 2 คนยังไม่แต่งงาน แยกกันอยู่คนละที่ บิดามารดาอยู่ด้วยกัน 2 คนที่ต่างจังหวัด
- ช่วงมารดาป่วยไม่นาน 2 คนเป็นคนดูแล แต่ตอนเข้าโรงพยาบาลครั้งนี้คุณสมหญิงเป็นคนดูแลเป็นหลัก

### VDO

#### คำถาม

- ท่านจะมีแนวทางการให้คำปรึกษาแก่คุณสมหญิงอย่างไร

### Risk factors for pathological grief

Category	Details
Nature of death	- Death of child - Unexpected death - Severe suffering - Stigmatized illness
Relative's characteristic	- Psychiatric disorder - Repeated losses
Relationship	- Dependent
Supporting system	- High conflict in family - Poor support

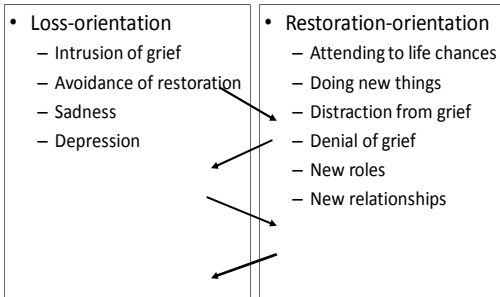
(Kissane and Zaider, 2015)

### Interventions for family

- **When a patient is dying**
  - Life review
  - Review of relationships with the ill member
  - Expression of gratitude for the good times shared
  - Completion of unfinished business
  - Saying farewell

(Lethborg and Kissane, 2015)

### Dual process model



(Stroebe and Schut, 1998)

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## การให้คำปรึกษาแก่ญาติที่มีภาวะเศร้าโศกเสียใจจากการที่ผู้ป่วยเสียชีวิต

ปเนต ผู้กฤตยาคามิ

ภาวะเศร้าโศกเสียใจจากการที่บุคคลอันเป็นที่รักเสียชีวิต (grief and bereavement) เป็นภาวะที่อาจเกิดขึ้นได้กับญาติของผู้ป่วยภายหลังจากผู้ป่วยเสียชีวิต ซึ่งในบางครั้งญาติจำเป็นต้องได้รับคำปรึกษาและการดูแลทางด้านจิตใจจากแพทย์เพื่อไม่ให้ภาวะเศร้าโศกเสียใจคงอยู่ต่อเนื่องเป็นเวลานานและส่งผลกระทบต่อการดำเนินชีวิตประจำวัน โดยหลักการให้คำปรึกษาแก่ญาติมีดังต่อไปนี้

### 1. การประเมินว่าญาติคนใดมีความเสี่ยงต่อการเกิดภาวะเศร้าโศกเสียใจจากการที่บุคคลอันเป็นที่รักเสียชีวิต

การประเมินความเสี่ยงสามารถทำได้ตั้งแต่ตอนที่ผู้ป่วยยังไม่เสียชีวิต ซึ่งหากแพทย์สามารถคาดการณ์ได้ว่าญาติของผู้ป่วยรายใดมีความเสี่ยงสูงและรีบให้คำปรึกษาและให้การดูแลทางด้านจิตใจตั้งแต่เนิ่นๆ จะช่วยลดความเศร้าโศกเสียใจให้ญาติได้ภายหลังที่ผู้ป่วยเสียชีวิตแล้ว โดยปัจจัยเสี่ยงต่อการเกิดภาวะเศร้าโศกเสียใจจากการที่บุคคลอันเป็นที่รักเสียชีวิตมีดังตารางที่ 1

ตารางที่ 1 ปัจจัยเสี่ยงต่อการเกิดภาวะเศร้าโศกเสียใจจากการที่บุคคลอันเป็นที่รักเสียชีวิต<sup>1</sup>

ประเภทของปัจจัยเสี่ยง	รายละเอียด
ลักษณะของการเสียชีวิตของผู้ป่วย	<ul style="list-style-type: none"> <li>- ผู้ป่วยเสียชีวิตตั้งแต่อายุยังน้อย เช่น การเสียชีวิตของบุตร</li> <li>- ผู้ป่วยเสียชีวิตอย่างกะทันหัน</li> <li>- ผู้ป่วยทุกข์ทรมานมาก่อนเสียชีวิต</li> <li>- ผู้ป่วยเสียชีวิตจากโรคที่เป็นตราบาป เช่น โรคเอดส์</li> </ul>
ลักษณะของญาติ	<ul style="list-style-type: none"> <li>- ญาติป่วยเป็นโรคทางจิตเวช เช่น โรคซึมเศร้า</li> <li>- ญาติวิตกกังวลง่าย</li> <li>- ญาติไม่มั่นใจตนเอง</li> <li>- ญาติเคยผ่านประสบการณ์การสูญเสียบุคคลอันเป็นที่รักมาบ่อยๆ</li> </ul>
ลักษณะความสัมพันธ์ของญาติกับผู้ป่วย	<ul style="list-style-type: none"> <li>- ญาติต้องพึ่งพิงผู้ป่วยมาก</li> </ul>
ลักษณะของครอบครัว	<ul style="list-style-type: none"> <li>- มีปัญหาครอบครัว</li> <li>- ญาติอยู่ตัวคนเดียวภายหลังผู้ป่วยเสียชีวิต</li> <li>- ไม่มีญาติคนอื่นๆให้การช่วยเหลือ</li> </ul>

หากพบว่าญาติคนใดมีปัจจัยเสี่ยงเหล่านี้หลายๆปัจจัย แพทย์ควรประเมินสภาพจิตใจของญาติและให้คำปรึกษาตั้งแต่เนิ่นๆ

## 2. การให้คำปรึกษาแก่ญาติเมื่อผู้ป่วยใกล้เสียชีวิต

เทคนิคหนึ่งที่อาจช่วยลดความเศร้าเสียใจให้ญาติได้คือการชวนญาติรำลึกถึงความสัมพันธ์ระหว่างญาติกับผู้ป่วยในช่วงชีวิตที่ผ่านมา โดยหากพบว่าญาติยังมีสิ่งใดที่อยากบอกหรืออยากทำให้ผู้ป่วย แต่ยังไม่มีโอกาสได้ทำแพทย์อาจช่วยส่งเสริมให้ญาติได้ทำตามความตั้งใจเพื่อไม่ให้มีสิ่งใดค้างคาใจญาติ ภายหลังจากผู้ป่วยเสียชีวิตแล้ว นอกจากนี้หากพบว่ามีสิ่งใดที่ดีที่ญาติได้เคยทำให้กับผู้ป่วยแพทย์สามารถชี้ให้ญาติเห็นหรือให้การชื่นชมได้ เทคนิคนี้อาจช่วยลดความรู้สึกผิดของญาติในกรณีที่ญาติรู้สึกว่าคุณเองดูแลผู้ป่วยได้ไม่ดีพอ<sup>2</sup>

เมื่ออาการของผู้ป่วยเข้าสู่ระยะสุดท้าย แพทย์ควรส่งเสริมให้ญาติและผู้ป่วยใช้เวลาช่วงสุดท้ายอยู่ด้วยกันอย่างเต็มที่เพื่อให้ญาติและผู้ป่วยได้มีโอกาสบอกความรู้สึกที่มีต่อกันรวมถึงการบอกลาก่อนที่ผู้ป่วยจะเสียชีวิต<sup>2</sup>

## 3. การให้คำปรึกษาแก่ญาติภายหลังจากผู้ป่วยเสียชีวิตแล้ว

หากญาติยังมีความรู้สึกเศร้าเสียใจภายหลังจากผู้ป่วยเสียชีวิตแล้ว แพทย์อาจให้คำปรึกษาโดยเริ่มจากเปิดโอกาสให้ญาติได้ระบายความรู้สึกเศร้าเสียใจพร้อมกับรับฟังอย่างตั้งใจ แพทย์อาจใช้เทคนิคสะท้อนความรู้สึก เช่น เมื่อสังเกตเห็นผู้ป่วยมีน้ำตาคลอแพทย์อาจพูดว่า “ผมเข้าใจครับว่าคุณรู้สึกเสียใจ เพราะคุณพ่อมีความสำคัญกับคุณมาก” การที่ญาติได้ระบายความรู้สึกและมีผู้รับฟังอย่างเข้าใจจะช่วยบรรเทาความรู้สึกเศร้าเสียใจของญาติได้ เมื่อญาติได้ระบายความรู้สึกในระดับหนึ่งแล้วแพทย์อาจเปลี่ยนไปถามถึงความทรงจำดีๆที่ญาติมีต่อผู้ป่วยร่วมด้วยเพื่อไม่ให้ญาติหมกมุ่นอยู่กับความเศร้าเสียใจมากเกินไป นอกจากนี้การส่งเสริมให้ญาติได้พบปะกับญาติคนอื่น ๆ และการชวนคุยเรื่องการวางแผนจัดงานศพตามประเพณีอาจช่วยบรรเทาความรู้สึกเศร้าเสียใจให้ญาติได้<sup>1</sup>

## 4. การให้คำปรึกษาโดยใช้หลักการ dual process model of coping with loss (DPM)<sup>3</sup>

หลักการนี้มาจากแนวความคิดที่ว่าภายหลังจากผู้ป่วยเสียชีวิต ญาติอาจมีปฏิกริยาได้สองรูปแบบคือ

- 1) Loss-orientation ญาติยังคงเศร้าเสียใจเป็นอย่างมากเนื่องจากยังคงหมกมุ่นอยู่กับความคิดถึงผู้ป่วยที่เสียชีวิต

- 2) Restoration-orientation ญาติพยายามเบี่ยงเบนความสนใจจากความทุกข์โดยการจดจ่อกับการวางแผนจัดการเรื่องต่างๆในชีวิตประจำวัน

หากญาติมีปฏิริยาทั้งสองรูปแบบสลับกันไปมาอย่างสมดุล จะช่วยให้ระดับความเศร้าเสียใจมีไม่มากจนเกินไป และญาติยังสามารถวางแผนปรับตัวในการดำเนินชีวิตประจำวันโดยที่ปราศจากผู้ป่วยได้ แต่หากมีปฏิริยาในรูปแบบใดรูปแบบหนึ่งที่มากจนเกินไป เช่น ยังเศร้าเสียใจมากจนไม่สามารถดูแลบ้านหรือไปทำงานได้ หรือ พยายามลืมความเศร้าโดยการทำงานหนักจนไม่มีโอกาสได้ระบายความรู้สึกของตนเอง จะทำให้ภาวะเศร้าเสียใจยังคงอยู่อย่างต่อเนื่อง ดังนั้นในการให้คำปรึกษา แพทย์อาจถามถึงความคิดและความรู้สึกของญาติเพื่อเปิดโอกาสให้ญาติได้ระบายความรู้สึกเศร้าเสียใจอย่างเหมาะสมโดยระวังอย่าให้ญาติหมกมุ่นอยู่กับความรู้สึกนี้มากจนเกินไป จากนั้นจึงเปลี่ยนรูปแบบการถามเป็นการถามถึงการวางแผนการจัดการเรื่องต่างๆในชีวิตประจำวันเพื่อกระตุ้นให้ญาติสามารถปรับตัวดำเนินชีวิตต่อไปได้ภายหลังจากที่ผู้ป่วยเสียชีวิตแล้ว

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## เอกสารประกอบการอบรม



20 Oct 2017





20 Oct 2017

หัวข้อ : Basic principles of communication skills teaching

## Principles of Communication Skills Teaching

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### Goals

- After this session, participants will be able to :-
  - Explain key concepts of how to teach communication skills
  - Give examples of methods for communication skills teaching
  - Choose appropriate methods for communication skills teaching

### Outline

- Should we teach?
- What to teach?
- How to teach?

### Should We Teach?

- Systematic review of literature about communication skills teaching and learning in medicine
  - 180 articles between 1991 – 1998
  - Select 83 high and medium quality articles
  - Overwhelming evidence for positive effect of communication skills training.
  - Low scorers on pre-training test showed the greatest gain from the training.

Aspegren K. Teaching and learning communication skills in medicine: A review with quality grading of articles: BEME guide no. 2. Medical Teacher 1999;21(6):563 – 70.

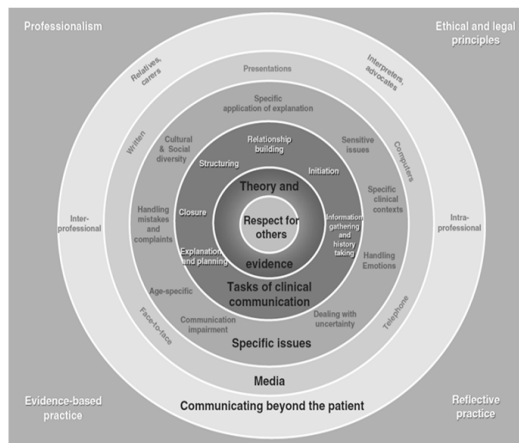
### What to Teach?

- จำเป็นหรือไม่ที่อาจารย์ต้องเรียนรู้เนื้อหาของ “ทักษะการสื่อสาร” ก่อนที่จะเข้าสู่วิธีการสอน
  - Experience: little formal training
  - Difficulty in accessing literature
  - Uncomfortable teaching without personal understanding
  - Framework for students' assessment

### What to Teach?

- UK consensus statement on the content of communication curricula in undergraduate medical education
  - Developed by an iterative process of discussion between 33 UK medical schools
  - Product: Communication curriculum wheel

Von Fragstein M, et al. UK consensus statement on the content of communication curricula in undergraduate medical education. Medical Education 2008;42:1100 – 1107.



## Theory and Evidence

- Awareness of the evidence base for communication skills on
  - Patient satisfaction
  - Wellbeing
  - Adherence and concordance
  - Physical outcomes
  - Psychological outcomes
  - Medico-legal issues
  - Patient safety

## Tasks and Skills of Communication

### Tasks

- Establish a relationship
- Initiation
- Gather information
- Elicit patient's view
- Explain
- ...
- Closing

### Skills

- Eye contact
- Facial expression
- Attentive listening
- Balancing open/close questions
- Facilitation
- Summarizing
- Checking patient's understanding

## Specific Issues

- Age-specific areas
- Cultural and social diversity
- Handling emotions
- Specific clinical contexts
- Specific application: informed consent, health promotion, behavior change
- Sensitive issues: break bad news, dying and bereavement, child abuse

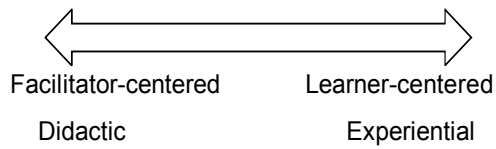
## Media

- Face-to-face communication
- Telephone communication
- Written communication
- Electronic communication

## General Principles for Communication Skills Teaching

- It is taught in clinical context.
- It is objective driven.
- It is based on behaviors and attitudes.
- It is learner-centered.
- It is interactive.
- It is based on objective observation.
- It has constructive feedback.
- It needs a safe learning environment.

## Teaching Methods



## Didactic Methods

- Lecture
- Assigned reading
- Discussion groups
- Demonstrations (live or videotaped)
- Seminars
- E-learning

## Experiential Learning

- Audio and video recordings and feedback
- Real patients
  - Pre-recorded videotaped consultations
  - Live interviews of patients
- Simulated patients
- Role play

## Summary

- Should we teach?
  - Yes
- What to teach?
  - Communication curriculum wheel
- How to teach?
  - Didactic versus experiential learning



20 Oct 2017

## หัวข้อ : Facilitation techniques

## การใช้ทักษะ Facilitation ในการสอนการสื่อสาร

ผศ.พญ.กษณา รักษาภรณ์

การสอนทักษะการสื่อสารกับผู้ป่วยนั้นต้องกระตุ้นให้เกิดการเปลี่ยนแปลงในจิตใจ เพื่อเปลี่ยนแปลงทัศนคติ จึงจะส่งผลต่อการแสดงพฤติกรรมสื่อสารทั้งหมดได้ เนื่องจากการแสดงออกในการสื่อสารกับผู้ป่วยนั้นไม่ใช่เพียงคำพูด แต่ยังรวมถึงภาษากาย น้ำเสียง และอารมณ์ ความรู้สึกในเวลาสื่อสาร การเรียนรู้เพื่อสร้างการเปลี่ยนแปลงจากภายในจึงมีความสำคัญ เพื่อให้ทุกองค์ประกอบครบสมบูรณ์ ในที่นี้จะขอนำเสนอทักษะหนึ่งในการสอนให้เกิดการเปลี่ยนแปลงจากภายใน นั่นคือ facilitation

Facilitation นั้นเป็นคำกลางๆ ที่ใช้ในหลายวงการ หากไปค้นหาบทความจะได้มุมมองที่หลากหลายจากแต่ละวิชาชีพ ในที่นี้จะขอเน้นถึงหลักการที่จะนำมาประยุกต์ใช้ในการสอนทักษะการสื่อสารกับผู้ป่วยเป็นหลัก ซึ่งจะเป็นการสอนที่เน้นผู้เรียนเป็นศูนย์กลาง ผู้สอนไม่ได้ใช้การบอกเล่ามากนัก แต่กระตุ้นให้ผู้เรียนเกิดการคิด และได้เรียนรู้ด้วยตนเอง การออกแบบการสอนผู้สอนต้องมีความรู้ความเข้าใจในเนื้อหาเป็นอย่างดี และมีวัตถุประสงค์ของ session นั้นๆ ที่ชัดเจน มีทักษะการใช้คำถามที่กระตุ้นให้คิด ร่วมกับกิจกรรมให้ผู้เรียนมีส่วนร่วม และมีการควบคุมทิศทางของการแสดงความคิดเห็นเพื่อทำให้ผู้เรียนบรรลุวัตถุประสงค์เมื่อสิ้นสุดชั่วโมง โดยผู้สอนต้องวิเคราะห์ผู้เรียนด้วยว่า ได้เรียนรู้ไปพร้อมๆ กันในทิศทางที่ต้องการหรือไม่ เนื่องจากผู้เรียนอาจมีความรู้และทัศนคติพื้นฐานที่แตกต่างกัน ต้องหาจุดที่เป็นปัญหาซึ่งหากไขข้อข้องใจได้ตรงจุดจะเกิดการเปลี่ยนทัศนคติ ซึ่งนำไปสู่การเปลี่ยนแปลงพฤติกรรม และสร้างแรงบันดาลใจให้ผู้เรียนได้เรียนรู้เพิ่มเติมได้อีกมาก

## ทักษะที่พึงมีในการสอนด้วย facilitation

## 1. การสอนโดยใช้คำถาม

การใช้คำถามมีประโยชน์ในการสอนด้วย facilitation เพื่อประเมินความรู้ความเข้าใจ กระตุ้นให้มีส่วนร่วม ควบคุมทิศทางการอภิปรายให้บรรลุวัตถุประสงค์ และเพื่อให้ทุกคนได้สำรวจและทบทวนความคิดของตนเอง

การสอนโดยใช้คำถามที่มีประสิทธิภาพนั้นประกอบด้วย การตั้งคำถามที่ดี การฟังและการสังเกตที่ดี และการตอบสนองต่อคำตอบที่ดี โดยคำถามที่ดีนั้นจะต้องเข้าใจง่าย กระตุ้นการคิดวิเคราะห์และทำให้ผู้เรียนมีส่วนร่วมในบทเรียน โดยสามารถแบ่งความซับซ้อนของคำถามได้ตามระดับของ Bloom taxonomy ดังนี้

1. Remember ลักษณะการถามความจำแบบนี้ใช้เพื่อทดสอบความรู้ของผู้เรียน และกระตุ้นการมีส่วนร่วมได้ง่าย โดยเริ่มจากคำถามกว้างๆ ง่ายๆ เพื่อสร้างบรรยากาศให้ผู้เรียนแสดงความคิดเห็น
2. Understand ถามเพื่อตรวจสอบความเข้าใจของผู้เรียน ใช้ในตอนเริ่มต้นเพื่อดูพื้นฐานความรู้ของผู้เรียน หรือระหว่างการเรียนรู้การสอนเพื่อให้มั่นใจว่าผู้เรียนทั้งหมดเข้าใจไปในทิศทางเดียวกัน
3. Apply ให้ตีความหมาย และประยุกต์ใช้ความรู้ในสถานการณ์ได้

4. Analyze เพื่อสร้างความเชื่อมโยงของความคิด วิเคราะห์ปัญหา แยกแยะความแตกต่าง
5. Evaluate เพื่อให้ผู้เรียนรวบรวมความรู้ความเข้าใจ เพื่อแสดงความคิดเห็นประเมินสถานการณ์ได้ เช่นการให้วิพากษ์กรณีศึกษา
6. Create เพื่อเปิดโอกาสให้ออกแบบ แสดงถึงกระบวนการคิดขั้นสูง เช่น ถ้าต้องพูดประโยคให้คำแนะนำผู้ป่วยใหม่ จะพูดอย่างไร

นอกจากทักษะการตั้งคำถามแล้ว การฟังอย่างตั้งใจ ร่วมกับการสังเกตพฤติกรรม จะช่วยให้ทราบแนวคิด ความเข้าใจ และสามารถดึงความสนใจของผู้เรียนได้มากขึ้น นอกจากนี้ยังช่วยแก้ไขข้อบกพร่องใจที่อาจเป็นพื้นฐานที่หากแก้ถูกจุด จะสามารถเปลี่ยนทัศนคติและพฤติกรรมที่แสดงออกได้โดยง่าย โดยผู้สอนควรใช้เวลาผู้เรียนได้คิด รอคำตอบด้วยท่าทีที่ไม่กดดัน แสดงออกถึงความสนใจที่จะฟังคำตอบสังเกตภาษากายของผู้ที่อยากหรือไม่อยากตอบ และสังเกตในขณะที่ตอบว่าผู้ตอบมีความรู้สึกละอายใจหรือไม่ ส่วนสรุปตัดสิน เนื่องจากผู้สอนมีประสบการณ์มากกว่า มักคิดได้เร็วกว่าผู้เรียนที่กำลังคิดหาคำตอบ จึงไม่ควรประเมินคุณค่าของคำตอบเร็วเกินไป และระวังท่าทีการแสดงออกด้วยอวัจนภาษาของตนเอง ซึ่งอาจทำให้ผู้ที่กำลังตอบอยู่เสียความมั่นใจ และไม่กล้าตอบอีกก็เป็นได้

## II. ทักษะในการบริหารจัดการห้องเรียน

การบริหารจัดการห้องเรียนนั้นรวมถึงตั้งแต่การออกแบบที่นั่งที่ให้ทุกคนได้มีส่วนร่วม การตั้งวัตถุประสงค์การสอน การออกแบบแผนการสอน การควบคุมบรรยากาศการเรียนการสอน และการแก้ไขปัญหาเฉพาะหน้าในขณะสอน

การออกแบบที่นั่งนั้นขึ้นกับขนาดของชั้นเรียน ควรออกแบบโดยระวังไม่ให้มีโต๊ะขนาดใหญ่มาขวางกั้นปฏิสัมพันธ์ของผู้เรียนและผู้สอน และผู้สอนสามารถมองเห็น สังเกต สบตา เรียกถามผู้เรียนได้ทุกคน หากเป็นชั้นเรียนขนาดใหญ่ อาจแบ่งเป็นกลุ่มย่อยๆ เพื่อให้ผู้เรียนได้มีปฏิสัมพันธ์กันเองขณะกิจกรรมกลุ่มได้ด้วย

การตั้งวัตถุประสงค์การสอนนั้นแนะนำให้เป็นวัตถุประสงค์เชิงพฤติกรรมที่มีความชัดเจน เนื่องจากการสอนทักษะการสื่อสารเป็นเรื่องที่บางครั้งเกี่ยวข้องกับอารมณ์และความรู้สึก หากผู้สอนไม่ตั้งวัตถุประสงค์ที่เป็นรูปธรรมชัดเจนอาจทำให้ชั่วโมงสอนนั้นบรรลุตามวัตถุประสงค์ได้ยาก

การออกแบบแผนการสอน ต้องมีความยืดหยุ่น เนื่องจากบางครั้งมีการอภิปรายในประเด็นที่ไม่ได้วางแผนไว้ แต่มีความสำคัญ ผู้สอนควรมีการปรับแผนการสอนให้เหมาะสมได้อย่างทันท่วงที

การควบคุมบรรยากาศการเรียนการสอน ควรสร้างบรรยากาศที่ผู้เรียนรู้สึกว่าจะตอบคำถามและแสดงความคิดเห็นได้อย่างปลอดภัย กระตุ้นการมีส่วนร่วม แก้ไขสถานการณ์ได้หากมีผู้เรียนที่ไม่สนใจ ทำสิ่งอื่นในชั้นเรียน ไม่มีส่วนร่วมในการตอบคำถามและแสดงความคิดเห็น หรือมีส่วนร่วมมากเกินไป มีแนวคิดที่แตกต่าง หรือนำการอภิปรายออกนอกระบบวัตถุประสงค์

### เอกสารอ้างอิงสำหรับศึกษาเพิ่มเติม

1. Edmunds S, Brown G. Effective small group learning: AMEE Guide No. 48. Medical teacher. 2010 Sep 1;32(9):715-26.
2. Bate E, Hommes J, Duviols R, Taylor DC. Problem-based learning (PBL): Getting the most out of your students—Their roles and responsibilities: AMEE Guide No. 84. Medical teacher. 2014 Jan 1;36(1):1-2.
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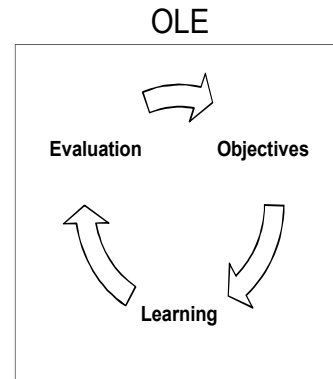
20 Oct 2017

หัวข้อ : How to assess communication Skills

## How to Assess Communication Skills

เชิดศักดิ์ ไอรณรัตน์

ภาควิชาศัลยศาสตร์ คณะแพทยศาสตร์ศิริราชพยาบาล



### Goals

After this session, participants will be able to:

- Explain key factors leading to valid assessment
- Give examples of tools for communication skills assessment
- Choose appropriate tools for communication skills assessment

### Outline

- Basic considerations in assessment
- Commonly used assessment tools
- Practice using the instruments

### Assessment and Instructional Process

- Placement
  - Aims at determining the readiness of students for the planned instruction
- Formative
  - Aims at providing feedback to students and teachers concerning learning successes and failures
- Summative
  - Aims at determining the extent to which instructional goals have been achieved; used primarily for assigning grades

### Assessment Approaches

Does

Shows how

Knows how

Knows

### Miller's Pyramid



## Assessment Tools

- A systematic review of instruments assessing patient-centered communication
  - Fourteen instruments
  - Cover wide range of settings and patient populations
  - Number of items: 6 – 20
  - Use in both formative and summative settings
  - Raters: patients, SP, instructors

Brouwers M, et al. Assessing patient-centered communication in teaching: A systematic review of instruments. *Medical Education* 2017, doi 10.1111/medu.13375.

## Assessment Tools

- Three examples
  1. Calgary-Cambridge Guide
  2. Gap-Kalamazoo Communication Skills Assessment Form (GKCSAF)
  3. Revised UIC Communication and Interpersonal Skills (RUCIS)

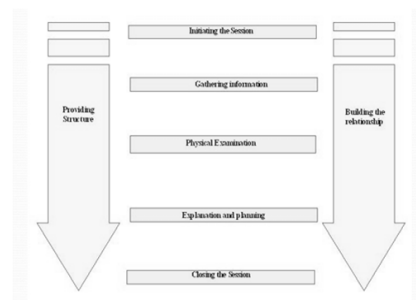
## Calgary-Cambridge Guides

Kurtz SM, Silverman JD, Draper J. Teaching and learning communication skills in medicine. Radcliffe Medical Press (Oxford), 1998.

Burt et al. Assessing communication quality of consultations in primary care: initial reliability of the Global Consultation Rating Scale, based on the Calgary-Cambridge Guide to the medical interview, *BMJ Open* 2014; 4: e004339.

- <http://www.skillscascade.com/handouts/CalgaryCambridgeGuide.pdf>

## Calgary-Cambridge Guides for Effective Physician-Patient Communication



Kurtz S, Silverman J, Benson J, Draper J. Marrying content and process in clinical method teaching: Enhancing the Calgary-Cambridge guides. *Acad Med.* 2003; 78(8): 802-9.

## GKCSAF

- Peterson EB, et al. The reliability of a modified Kalamazoo Consensus Statement Checklist for assessing the communication skills of multidisciplinary clinicians in the simulated environment, *Patient Education and Counseling* 2014; 96: 411 – 8.

## GKCSAF

- A. Builds a relationship
- B. Opens the discussion
- C. Gathers information
- D. Understands the patient's and families
- E. Shares information
- F. Reaches agreement
- G. Provides closure
- H. Demonstrates empathy
- I. Communicates accurate information

## RUCIS

- Iramaneerat C, et al. Evaluating the effectiveness of rating instruments for a communication skills assessment of medical residents. Adv Health Sci Educ Theory Pract 2009;14 : 575 -94.

## RUCIS

- |                                    |                               |
|------------------------------------|-------------------------------|
| 1. Friendly communication          | 7. Encourage questions        |
| 2. Respectful treatment            | 8. Clear explanation          |
| 3. Listening                       | 9. Physical examination       |
| 4. Honest communication            | 10. Vocabulary                |
| 5. Interest in patient as a person | 11. Sensitive subject matters |
| 6. Discussion options              | 12. Receptiveness to feedback |
|                                    | 13. Overall impression        |

## Summary

- Basic considerations in assessment
  - Formative and summative
  - Knows, knows how, shows how, does
- Commonly used assessment tools
  - Calgary-Cambridge guide
  - Gap-Kalamazoo form
  - RUCIS scale
- Practice using the instruments

*“Purposeful assessment drives instruction and affects learning.”*

Wisconsin's guiding principles for teaching and learning



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## CALGARY - CAMBRIDGE GUIDE TO THE MEDICAL INTERVIEW – COMMUNICATION PROCESS

### INITIATING THE SESSION

#### Establishing initial rapport

1. **Greets** patient and obtains patient's name
2. **Introduces** self, role and nature of interview; obtains consent if necessary
3. **Demonstrates respect** and interest, attends to patient's physical comfort

#### Identifying the reason(s) for the consultation

4. **Identifies** the patient's problems or the issues that the patient wishes to address with appropriate **opening question** (e.g. "What problems brought you to the hospital?" or "What would you like to discuss today?" or "What questions did you hope to get answered today?")
5. **Listens** attentively to the patient's opening statement, without interrupting or directing patient's response
6. **Confirms list and screens** for further problems (e.g. "so that's headaches and tiredness; anything else.....?")
7. **Negotiates agenda** taking both patient's and physician's needs into account

### GATHERING INFORMATION

#### Exploration of patient's problems

8. **Encourages patient to tell the story** of the problem(s) from when first started to the present in own words (clarifying reason for presenting now)
9. **Uses open and closed questioning technique**, appropriately moving from open to closed
10. **Listens** attentively, allowing patient to complete statements without interruption and leaving space for patient to think before answering or go on after pausing
11. **Facilitates** patient's responses verbally and non-verbally e.g. use of encouragement, silence, repetition, paraphrasing, interpretation
12. **Picks up** verbal and non-verbal **cues** (body language, speech, facial expression, affect); **checks out and acknowledges** as appropriate
13. **Clarifies** patient's statements that are unclear or need amplification (e.g. "Could you explain what you mean by light headed")
14. **Periodically summarises** to verify own understanding of what the patient has said; invites patient to correct interpretation or provide further information.
15. **Uses** concise, **easily understood questions and comments**, avoids or adequately explains jargon
16. **Establishes dates and sequence** of events

#### Additional skills for understanding the patient's perspective

17. Actively **determines and appropriately explores**:
  - patient's **ideas** (i.e. beliefs re cause)
  - patient's **concerns** (i.e. worries) regarding each problem
  - patient's **expectations** (i.e., goals, what help the patient had expected for each problem)
  - effects: how each problem **affects** the patient's life
18. **Encourages patient to express feelings**

## PROVIDING STRUCTURE

### Making organisation overt

19. **Summarises** at the end of a specific line of inquiry to confirm understanding before moving on to the next section

20. Progresses from one section to another using **signposting, transitional statements**; includes rationale for next section

### Attending to flow

21. Structures interview in **logical sequence**

22. Attends to **timing** and keeping interview on task

---

## BUILDING RELATIONSHIP

### Using appropriate non-verbal behaviour

23. **Demonstrates appropriate non-verbal behaviour**

- eye contact, facial expression
- posture, position & movement
- vocal cues e.g. rate, volume, tone

24. If reads, writes **notes** or uses computer, does **in a manner that does not interfere with dialogue or rapport**

25. **Demonstrates appropriate confidence**

### Developing rapport

26. **Accepts** legitimacy of patient's views and feelings; is not judgmental

27. **Uses empathy** to communicate understanding and appreciation of the patient's feelings or predicament; overtly **acknowledges patient's views** and feelings

28. **Provides support**: expresses concern, understanding, willingness to help; acknowledges coping efforts and appropriate self care; offers partnership

29. **Deals sensitively** with embarrassing and disturbing topics and physical pain, including when associated with physical examination

### Involving the patient

30. **Shares thinking** with patient to encourage patient's involvement (e.g. "What I'm thinking now is....")

31. **Explains rationale** for questions or parts of physical examination that could appear to be non-sequiturs

32. During **physical examination**, explains process, asks permission

---

**EXPLANATION AND PLANNING****Providing the correct amount and type of information**

33. **Chunks and checks:** gives information in manageable chunks, checks for understanding, uses patient's response as a guide to how to proceed
34. **Assesses patient's starting point:** asks for patient's prior knowledge early on when giving information, discovers extent of patient's wish for information
35. **Asks patients what other information would be helpful** e.g. aetiology, prognosis
36. **Gives explanation at appropriate times:** avoids giving advice, information or reassurance prematurely

**Aiding accurate recall and understanding**

37. **Organises explanation:** divides into discrete sections, develops a logical sequence
38. **Uses explicit categorisation or signposting** (e.g. "There are three important things that I would like to discuss. 1st..." "Now, shall we move on to.")
39. **Uses repetition and summarising** to reinforce information
40. **Uses concise, easily understood language,** avoids or explains jargon
41. **Uses visual methods of conveying information:** diagrams, models, written information and instructions
42. **Checks patient's understanding** of information given (or plans made): e.g. by asking patient to restate in own words; clarifies as necessary

**Achieving a shared understanding; incorporating the patient's perspective**

43. **Relates explanations to patient's illness framework:** to previously elicited ideas, concerns and expectations
44. **Provides opportunities and encourages patient to contribute:** to ask questions, seek clarification or express doubts; responds appropriately
45. **Picks up verbal and non-verbal cues** e.g. patient's need to contribute information or ask questions, information overload, distress
46. **Elicits patient's beliefs, reactions and feelings** re information given, terms used; acknowledges and addresses where necessary

**Planning: shared decision making**

47. **Shares own thinking as appropriate:** ideas, thought processes, dilemmas
48. **Involves patient** by making suggestions rather than directives
49. **Encourages patient to contribute their thoughts:** ideas, suggestions and preferences
50. **Negotiates a mutually acceptable plan**
51. **Offers choices:** encourages patient to make choices and decisions to the level that they wish
52. **Checks with patient** if accepts plans, if concerns have been addressed
-

**CLOSING THE SESSION****Forward planning**

53. **Contracts** with patient re next steps for patient and physician

54. **Safety nets**, explaining possible unexpected outcomes, what to do if plan is not working, when and how to seek help

**Ensuring appropriate point of closure**

55. **Summarises session** briefly and clarifies plan of care

56. **Final check** that patient agrees and is comfortable with plan and asks if any corrections, questions or other items to discuss

**OPTIONS IN EXPLANATION AND PLANNING (includes content)****IF discussing investigations and procedures**

57. Provides clear information on procedures, eg, what patient might experience, how patient will be informed of results

58. Relates procedures to treatment plan: value, purpose

59. Encourages questions about and discussion of potential anxieties or negative outcomes

**IF discussing opinion and significance of problem**

60. Offers opinion of what is going on and names if possible

61. Reveals rationale for opinion

62. Explains causation, seriousness, expected outcome, short and long term consequences

63. Elicits patient's beliefs, reactions, concerns re opinion

**IF negotiating mutual plan of action**

64. Discusses options eg, no action, investigation, medication or surgery, non-drug treatments (physiotherapy, walking aides, fluids, counselling, preventive measures)

65. Provides information on action or treatment offered

name  
steps involved, how it works  
benefits and advantages  
possible side effects

66. Obtains patient's view of need for action, perceived benefits, barriers, motivation

67. Accepts patient's views, advocates alternative viewpoint as necessary

68. Elicits patient's reactions and concerns about plans and treatments including acceptability

69. Takes patient's lifestyle, beliefs, cultural background and abilities into consideration

70. Encourages patient to be involved in implementing plans, to take responsibility and be self-reliant

71. Asks about patient support systems, discusses other support available

**References:**

**Kurtz SM, Silverman JD, Draper J (1998) Teaching and Learning Communication Skills in Medicine. Radcliffe Medical Press (Oxford)**

**Silverman JD, Kurtz SM, Draper J (1998) Skills for Communicating with Patients. Radcliffe Medical Press (Oxford)**

## Appendix

## Gap-Kalamazoo Communication Skills Assessment Form\* – Faculty/Peer Assessment

Date:	Your Name:	Your Title:
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Title of Case:	Title of Conversation:
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How well did the participant(s) do the following (please select one):

	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
<b>A: Builds a relationship (includes the following):</b> <ul style="list-style-type: none"> <li>• Greets and shows interest in the patient's family</li> <li>• Uses words that show care and concern throughout the interview</li> <li>• Uses tone, pace, eye contact, and posture that show care and concern</li> <li>• Responds explicitly to patient and family statements about ideas and feelings</li> </ul>					
<b>B: Opens the discussion (includes the following):</b> <ul style="list-style-type: none"> <li>• Allows patient and family to complete opening statement without interruption</li> <li>• Asks "is there anything else?" to elicit full set of concerns</li> <li>• Explains and/or negotiates an agenda for the visit</li> </ul>					
<b>C: Gathers information (includes the following):</b> <ul style="list-style-type: none"> <li>• Addresses patient and family statements using open-ended questions</li> <li>• Clarifies details as necessary with more specific or "yes/no" questions</li> <li>• Summarizes and gives family opportunity to correct or add information</li> <li>• Transitions effectively to additional questions</li> </ul>					
<b>D: Understands the patient's and families perspective (includes the following):</b> <ul style="list-style-type: none"> <li>• Asks about life events, circumstances, other people that might affect health</li> <li>• Elicits patient's and family's beliefs, concerns, and expectations about illness and treatment</li> </ul>					
<b>E: Shares information (includes the following):</b> <ul style="list-style-type: none"> <li>• Assesses patient's/family's understanding of problems and desire for more info</li> <li>• Explains using words that family can understand</li> <li>• Asks if family has any more questions</li> </ul>					
<b>F: Reaches agreement (includes the following):</b> <ul style="list-style-type: none"> <li>• Includes family in choices and decisions to the extent they desire</li> <li>• Checks for mutual understanding of diagnostic and/or treatment plans</li> <li>• Asks about acceptability of diagnostic and/or treatment plans</li> <li>• Identifies additional resources as appropriate</li> </ul>					
<b>G: Provides closure (includes the following):</b> <ul style="list-style-type: none"> <li>• Asks if patient and family have questions, concerns or other issues</li> <li>• Summarizes</li> <li>• Clarifies future time when progress will again be discussed</li> <li>• Provides appropriate contact information if interim questions arise</li> <li>• Acknowledges patient and family, and closes interview</li> </ul>					
<b>H. Demonstrates Empathy (includes the following):</b> <ul style="list-style-type: none"> <li>• Clinician's demeanor is appropriate to the nature of the conversations</li> <li>• Shows compassion and concerns</li> <li>• Identifies/labels/validates patient's and family's emotional responses</li> <li>• Responds appropriately to patients and family's emotional cues</li> </ul>					
<b>I: Communicates accurate information (includes the following):</b> <ul style="list-style-type: none"> <li>• Accurately conveys the relative seriousness of the patient's condition</li> <li>• Takes other participating clinician's input into account</li> <li>• Clearly conveys expected disease course</li> <li>• Clearly presents and explains options for future care</li> <li>• Gives enough clear information to empower decision making</li> </ul>					

\*Adapted from: Essential Elements: The Communication Checklist, © 2001 Kalamazoo Consensus Statement Group, and from: Rider EA. Interpersonal and Communication Skills. In: Rider EA, Nawotniak RH. *A Practical Guide to Teaching and Assessing the ACGME Core Competencies, 2nd edition*. Marblehead, MA: HCPro, Inc., 2010. © 2010 HCPro, Inc. Used with permission. Contacts: Elizabeth Rider, MSW, MD - elizabeth\_rider@hms.harvard.edu (member, Kalamazoo Consensus Statement Group) and Aaron Calhoun, MD - aaron.calhoun@louisville.edu (PERCS Program)



**What did the participant(s) do best? (Please pick three choices)**

- 
- Builds a Relationship
  - Opens the Discussion
  - Gathers Information
  - Understands the Patient's and Family's Perspective
  - Shares Information
  - Reaches Agreement
  - Provides Closure
  - Demonstrates Empathy
  - Communicates Accurate Information
- 

**Why did you choose those particular answers?****In which domains could the participant(s) improve? (Please pick three choices)**

- 
- Builds a Relationship
  - Opens the Discussion
  - Gathers Information
  - Understands the Patient's and Family's Perspective
  - Shares Information
  - Reaches Agreement
  - Provides Closure
  - Demonstrates Empathy
  - Communicates Accurate Information
- 

**What could have been done better?**

\*Adapted from: Essential Elements: The Communication Checklist, © 2001 Kalamazoo Consensus Statement Group, and from: Rider EA. Interpersonal and Communication Skills. In: Rider EA, Nawotniak RH. *A Practical Guide to Teaching and Assessing the ACGME Core Competencies, 2nd edition*. Marblehead, MA: HCPro, Inc., 2010. © 2010 HCPro, Inc. Used with permission. Contacts: Elizabeth Rider, MSW, MD - elizabeth\_rider@hms.harvard.edu (member, Kalamazoo Consensus Statement Group) and Aaron Calhoun, MD - aaron.calhoun@louisville.edu (PERCS Program)

## Revised UIC Communication and Interpersonal Skills Scale

Please choose the option that best describes how you feel toward the resident's communication skills. Some items also have a 'not applicable' option. Select this option when the context of the case does not allow you to observe that aspect of the resident's performance.

1. Friendly communication	<input type="checkbox"/> You <u>did not greet me, or greeted me perfunctorily, or communicated with me rudely</u> during the encounter. <input type="checkbox"/> Your greeting and/or behavior during the encounter was generally <u>polite but impersonal or distant</u> . <input type="checkbox"/> You greeted me warmly and communicated with me in a <u>friendly, personal manner</u> throughout the encounter. <input type="checkbox"/> Your greeting and overall communication were friendly and compassionate. Your tone of voice was appropriate for the situation. Overall, you <u>created an exceptionally warm and friendly environment</u> that made me <u>feel comfortable</u> to tell you all of my problems.
2. Respectful treatment	<input type="checkbox"/> You showed an <u>obvious sign of disrespect</u> during the encounter. You <u>treated me as an inferior</u> . <input type="checkbox"/> You did not show disrespect to me. However, I observed some <u>signs of condescending behavior</u> . Although I believe it was <u>unintentional</u> , it made me feel that I was not at the same level with you. <input type="checkbox"/> You gave <u>several indications of respecting me</u> . If there was a physical exam, this includes draping me appropriately. <input type="checkbox"/> You were exceptionally respectful throughout the encounter. Your <u>verbal and nonverbal</u> communication showed <u>respect for my privacy, my opinions, my rights, and my socioeconomic status</u> .
3. Listening to my story	<input type="checkbox"/> You <u>rarely gave me any opportunity to tell my story or frequently interrupted me</u> while I was talking, not allowing me to finish what I said. Sometimes I felt you were not paying attention (for example, <u>you asked for information that I already provided</u> ). <input type="checkbox"/> You let me tell my story without interruption, or only <u>interrupted appropriately</u> and respectfully. You seemed to pay attention to my story and <u>responded to what I said</u> appropriately. <input type="checkbox"/> You allowed me to tell my story without interruption, responded appropriately to what I said, and <u>asked thoughtful</u>

	<p>questions to encourage me to tell more of my story.</p> <p><input type="checkbox"/> You were an exceptional listener. You encouraged me to tell my story and checked your understanding by <u>restating important points</u>.</p>
4. Honest communication	<p><input type="checkbox"/> You <u>did not seem truthful and frank</u>. I felt that there might be something that you were trying to hide from me.</p> <p><input type="checkbox"/> You <u>did not seem to hide any critical information</u> from me.</p> <p><input type="checkbox"/> You explained the facts of the situation <u>without trivializing negative information or possibilities</u> (e.g., side effects, complications, failure rates).</p> <p><input type="checkbox"/> You were exceptionally frank and honest. You <u>fully explained the positive and negative aspects</u> of my condition. You openly <u>acknowledged your own lack of knowledge or uncertainty</u>, and things you would have to consult with others. When appropriate, you also suggested I seek a <u>second opinion</u>.</p> <p><input type="checkbox"/> <b>Not applicable.</b> There was no information for the resident to provide.</p>
5. Interest in me as a person.	<p><input type="checkbox"/> You never showed interest in me as a person. You <u>only focused on the disease</u> or medical issue.</p> <p><input type="checkbox"/> In addition to talking about my medical issue, you spent some time <u>getting to know me as a person</u>.</p> <p><input type="checkbox"/> You spent some time exploring <u>how my medical issue affects my personal or social life</u>.</p> <p><input type="checkbox"/> You were exceptionally interested in me as a person. You not only explored how my medical problem affects my personal and social life, but also <u>showed your willingness to help me address those challenges</u>.</p>
6. Discussion of options/plans	<p><input type="checkbox"/> You <u>did not explain any options or plans</u>, you just told me what you would do without asking for my opinion.</p> <p><input type="checkbox"/> You explained options to me, but <u>did not involve me in decision making</u>. If you <u>solicited my opinion</u>, you just <u>ignored it</u>. <u>You made all the decisions for me</u> based on your medical opinion.</p> <p><input type="checkbox"/> You discussed options with me, made recommendations, <u>solicited my opinion</u> regarding the options/plans, and <u>incorporated my opinion into your medical planning</u>.</p>

	<input type="checkbox"/> You not only solicited my input, but also <u>explored the reasons for my choice and showed your understanding and respect for my decisions</u> by negotiating a mutually agreeable plan.
	<input type="checkbox"/> <b>Not applicable.</b> There were no decisions to be made in this case.
7. Encouraging my questions	<input type="checkbox"/> You <u>did not solicit questions</u> , or frequently <u>avoided my questions</u> , or did not provide helpful answers.
	<input type="checkbox"/> You sometimes asked if I had questions, but <u>seldom waited</u> at least 5 seconds to allow me to formulate questions. You <u>addressed my questions briefly</u> without avoiding them.
	<input type="checkbox"/> You <u>actively encouraged me to ask questions</u> , <u>paused to allow me to formulate them</u> , and provided <u>clear and sufficient answers</u> to all of my questions.
	<input type="checkbox"/> You actively encouraged me to ask questions several times during the encounter, with <u>sufficient wait time</u> . You spent significant time and effort to answer my questions clearly and <u>confirmed that I understood the answer</u> and that my concerns were addressed.
8. Providing clear explanations	<input type="checkbox"/> You <u>rarely explained things</u> to me; you <u>did not help me better understand my situation</u> .
	<input type="checkbox"/> You gave me only <u>brief explanations</u> of my situation; you did not help me understand what would happen next.
	<input type="checkbox"/> You gave me a <u>full and understandable explanation</u> of my situation, pertinent findings, and important next steps.
	<input type="checkbox"/> You gave me a full explanation of my situation, your thinking about it and your recommendation, and <u>probed my understanding</u> by letting me summarize pertinent information.
	<input type="checkbox"/> <b>Not applicable.</b> There was nothing to be explained in this case.
9. Physical examination	<input type="checkbox"/> You <u>never or rarely warned me</u> about what you were <u>going to do</u> with my body. You also never or <u>rarely explained what you found</u> from the physical examination.
	<input type="checkbox"/> You <u>did not warn me</u> about what you were going to do with my body, OR <u>did not explain to me pertinent findings</u> (both negative and positive) from your physical examination.
	<input type="checkbox"/> You <u>told me what you were going to do to my body AND described what you found</u> .

	<p><input type="checkbox"/> You helped me understand clearly what you were going to do to my body. You also provided <u>clear explanation of what you found</u> from the physical examination and <u>the implications of your findings</u> for my situation.</p> <p><input type="checkbox"/> <b>Not applicable.</b> There was no physical examination in this case.</p>
10. Appropriate vocabulary	<p><input type="checkbox"/> You used vocabulary that was too simple or too complex for me, or <u>frequently used medical terms without explaining them</u> to me. Sometimes I could not understand what you told me without asking for explanations of terms you used.</p> <p><input type="checkbox"/> Your vocabulary was generally appropriate but you <u>sometimes inadvertently used medical terms without explaining them</u> to me.</p> <p><input type="checkbox"/> Your vocabulary was appropriate and if needed you provided <u>brief explanations of any medical terms you used without need for prompting</u>.</p> <p><input type="checkbox"/> Your vocabulary was appropriate and you <u>always provided clear and full explanation of relevant medical terms</u> you used. In addition, you helped me <u>better my understanding</u> of my condition with the medical terms you explained to me.</p>
11. Sensitive subject matters (e.g., sexual history, tobacco/alcohol/drug use, religious/cultural issues, giving bad news, or difficult emotional states)	<p><input type="checkbox"/> You <u>never warned me</u> before approaching sensitive subject matters. You seemed judgmental and clearly <u>expressed your disapproval of my positions or feelings</u>, making me feel uncomfortable about discussing these subjects or feelings with you.</p> <p><input type="checkbox"/> You were careful and nonjudgmental in discussing sensitive subject matters. However, you <u>did not express understanding</u> of my feelings and <u>did not provide much emotional support</u>.</p> <p><input type="checkbox"/> You were sensitive about discussing difficult subjects and were respectful of my feelings. I never sensed that you were judgmental or disapproving of my positions or feelings on these subjects. You <u>showed empathic understanding</u> of my position or feelings and provided appropriate <u>emotional support</u>.</p> <p><input type="checkbox"/> You were unusually empathic, sensitive and respectful of me and of my feelings and provided exceptional emotional support. In addition, you <u>verbally reflected these back to me</u> (e.g., “You sound sad”) to show your understanding.</p> <p><input type="checkbox"/> <b>Not applicable.</b> There were no sensitive subject matters in this case.</p>

12. Receptiveness to feedback	<input type="checkbox"/> You <u>did not seem open to my feedback</u> about your performance. You <u>responded defensively</u> or dismissively to many of my comments.
	<input type="checkbox"/> You listened to my feedback agreeably but passively. You <u>did not actively participate</u> during the feedback session.
	<input type="checkbox"/> You were able to <u>describe some of your own effective and ineffective behaviors</u> , were attentive to my comments, and had an <u>open discussion with me about alternative behaviors</u> .
	<input type="checkbox"/> You <u>actively solicited additional feedback</u> and <u>showed signs of integrating my feedback</u> into your behavioral repertoire. For example, you tried to role-play the communication techniques I suggested.
	<input type="checkbox"/> <b>Not applicable.</b> I provided no feedback.
13. Do I want to see you again as my personal physician?	<input type="checkbox"/> I did not feel comfortable in communicating with you at all. <u>I would rather see a different physician.</u>
	<input type="checkbox"/> I think <u>you were okay in general and might come see you again.</u>
	<input type="checkbox"/> I was impressed by the way you communicated with me. <u>I would like to see you again.</u>
	<input type="checkbox"/> I was very impressed with you. I think you are <u>one of the best physicians I have ever seen.</u> I would feel very comfortable discussing any medical problems with you, and <u>would recommend you to my friends.</u>



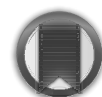
# BMJ Open Assessing communication quality of consultations in primary care: initial reliability of the Global Consultation Rating Scale, based on the Calgary-Cambridge Guide to the Medical Interview

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#### ABSTRACT

**Objectives:** To investigate initial reliability of the Global Consultation Rating Scale (GCRS: an instrument to assess the effectiveness of communication across an entire doctor-patient consultation, based on the Calgary-Cambridge guide to the medical interview), in simulated patient consultations.

**Design:** Multiple ratings of simulated general practitioner (GP)-patient consultations by trained GP evaluators.

**Setting:** UK primary care.

**Participants:** 21 GPs and six trained GP evaluators.

**Outcome measures:** GCRS score.

**Methods:** 6 GP raters used GCRS to rate randomly assigned video recordings of GP consultations with simulated patients. Each of the 42 consultations was rated separately by four raters. We considered whether a fixed difference between scores had the same meaning at all levels of performance. We then examined the reliability of GCRS using mixed linear regression models. We augmented our regression model to also examine whether there were systematic biases between the scores given by different raters and to look for possible order effects.

**Results:** Assessing the communication quality of individual consultations, GCRS achieved a reliability of 0.73 (95% CI 0.44 to 0.79) for two raters, 0.80 (0.54 to 0.85) for three and 0.85 (0.61 to 0.88) for four. We found an average difference of 1.65 (on a 0-10 scale) in the scores given by the least and most generous raters: adjusting for this evaluator bias increased reliability to 0.78 (0.53 to 0.83) for two raters; 0.85 (0.63 to 0.88) for three and 0.88 (0.69 to 0.91) for four. There were considerable order effects, with later consultations (after 15-20 ratings) receiving, on average, scores more than one point higher on a 0-10 scale.

**Conclusions:** GCRS shows good reliability with three raters assessing each consultation. We are currently developing the scale further by assessing a large sample of real-world consultations.

#### Strengths and limitations of this study

- The Global Consultation Rating Scale (GCRS) is based on the widely used Calgary-Cambridge guide to the medical interview, and is designed to evaluate a practitioner's communication skills across an entire consultation, linking the identification of potential training needs to an established approach to teaching communication skills.
- We considered evaluator bias and order effects to obtain a more robust assessment of the reliability of GCRS to evaluate communication competence within a particular consultation.
- A particular limitation is that our findings are based on the use of simulated patient consultations. This had an impact on our ability to assess the performance of GCRS to evaluate communication competence of individual doctors, rather than particular consultations. A full evaluation of the performance of GCRS requires the assessment of real-world consultations and we are undertaking this at present.

#### INTRODUCTION

During the past 30 years, an extensive research literature has defined the skills that enhance communication between doctor and patient. This evidence demonstrates the essential role that communication plays in high-quality healthcare by enabling more accurate, efficient and supportive interviews, by enhancing patient and professional experience and by improving health outcomes for patients. The use of specific communication skills has been shown to lead to improvements in symptom relief, in clinical outcomes and possibly in medicine adherence.<sup>1-6</sup> In light of these findings,



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there has been increasing pressure from professional medical bodies to improve the training and evaluation of doctors in communication.<sup>7-13</sup>

In order to evaluate doctors' communication skills effectively, tools with solid theoretical grounding and good psychometric properties are required. Various rating scales exist to assess doctor-patient consultations, which vary widely in their setting, approach and in the published details of their psychometric properties.<sup>14 15</sup> Perhaps for these reasons, none have become standard to use within the National Health Service (NHS), in spite of National Institute for Health and Care Excellence (NICE) standards which require that "Patients experience effective interactions with staff who have demonstrated competency in relevant communication skills."<sup>16</sup> Recently, there has been a move towards domain, or global, marking schemes (awarding overall marks to groupings of items) rather than itemised checklists, the suggestion being that checklists may reward thoroughness rather than competence and work better for novices than for experts.<sup>17</sup> Global marking schemes may be more useful in postgraduate assessments, improving professional authenticity. We have, therefore, developed the Global Consultation Rating Scale (GCRS), based on the Calgary-Cambridge guide to the medical interview, to evaluate the communication effectiveness of an entire doctor-patient consultation, using the domain marking approach.

At present, there is a dearth of assessment tools that robustly measure the overall communication skills of an individual general practitioner (GP) in real-world practice. While a number of existing tools may be used to assess doctor-patient communication, their suitability to assess a doctor's overall communication skills in day-to-day practice irrespective of the content of the consultation is limited and they do not link specifically to educational material commonly used in the UK for subsequent communication skills development. GCRS differs from some alternative instruments, such as the MAAS-Global, in its aim of measuring communication skills only, irrespective of clinical content, to provide an assessment of doctors' generic communication skills and to thereby enable targeted communication teaching. For example, 4 of the 17 items in the MAAS-Global specifically assess medical content related to history, examination, diagnosis and management and other communication items are highly specific to particular content areas.<sup>18</sup> In comparison, the 12 global areas of GCRS include only communication process skills without content. Following the approach of the Calgary-Cambridge guide from which it is derived, GCRS takes the standpoint that, although the context of the interaction changes and the content of the communication varies, the process skills themselves remain the same and can be evaluated independently. This, together with domain rather than individual skill marking, enables the assessment of communication skills across a wide variety of consultations, especially helpful in real-world

consultations where communication checklists cannot be specific and tailored for each case.

The Calgary-Cambridge guide to the medical interview<sup>1 19-21</sup> was developed by Silverman, Kurtz and Draper to delineate effective physician-patient communication skills and to provide an evidence-based structure for their analysis and teaching. Within the UK, over half of UK medical schools now use the Calgary-Cambridge approach in their communication skills programmes.<sup>22</sup> It has been widely translated and is used in the USA, Canada and Europe. It has been used to teach communication in general practice and specialist environments, at undergraduate and postgraduate levels.

Specific tools have been developed from the guide for the assessment of medical students, practising paediatricians, dentists, pharmacists and veterinary practitioners, as well as for specific components of the consultation such as explanation and planning in OSCE style examinations.<sup>23-25</sup> Before now however, there has been no validated method of using the Calgary-Cambridge consultation guide to assess complete consultations between qualified doctors and patients. This type of assessment is particularly important in postgraduate and continuing medical education in which the observation of whole consultations from real practice provides increased validity. In addition, for personal development and annual appraisal, a reliable validated assessment tool which also enables a specific link to targeted teaching of communication skills is particularly relevant. Our intention with GCRS is to develop an instrument capable of credibly evaluating a doctor's communication competence, identifying potential areas for improvement which could then be addressed directly with linked, tailored education, using the Calgary-Cambridge guide.

The aim of this study was to investigate the initial reliability of GCRS in simulated patient consultations such as those which might be used in training, as a precursor to its use with real patient consultations where GPs are assessed on their performance. To assess reliability, we asked five specific questions. These are detailed below, together with the reasons for their investigation:

- Does a fixed difference between scores in GCRS have the same meaning at all levels of performance? If it does not, GCRS scores may not be useful for distinguishing between performance uniformly at all levels of performance, and could require transformation prior to analysis.
- What is the reliability of GCRS in assessing individual consultations (with different numbers of raters per consultation)? One of two core questions: how consistently does GCRS perform in evaluating communication skills within a particular consultation, and how many raters are required to obtain performance estimates we are confident distinguish better from worse consultations?
- What is the reliability of GCRS in assessing individual doctors' performance across a number of



consultations (with different numbers of raters and consultations per doctor)? The second core question: how many consultations, and how many raters, do we need to evaluate a particular doctors' consultation skills such that we can differentiate them from their peers?

- D. Are some raters more generous than others in their assessments of consultations? Wide variation between the scores assigned by raters can lead to reduced reliability. Understanding whether systematic biases are present helps to inform whether to adjust reliability estimates for these or not.
- E. Does the order in which a consultation is rated affect the score? Psychological experiments have shown that the order in which information is presented can influence the way in which that information is processed.<sup>26</sup> Sequential order biases may present themselves either as an overall increase or decrease in scores throughout a judging period; or as observable effects of implicit comparisons being made between the previous and current items being judged.<sup>27 28</sup> Thus, a GCRS rater may use norm-based rather than criterion-based referencing when assigning scores as they proceed through the consultations being evaluated.

## METHODS

Trained GP raters watched video recordings of consultations between volunteer GPs and simulated patients and completed GCRS for each. We used videos from a previous study investigating the way in which GPs discussed taking statins to prevent cardiovascular disease with simulated patients trained to play one of two roles. The two roles differed in the extent of the actor's assertiveness in asking questions about proposed management. Both roles displayed sufficient cardiovascular risk to be eligible for statins according to current NICE recommendations. Actors were experienced in playing the role of simulated patients. They were provided with a detailed written role description, including notes on their intended style of response to questions. Actors rehearsed their roles before undertaking videotaped simulations with participant GPs. GPs (n=23) selected for recruitment to the original study varied in age, gender, length of time since qualification and nature of practice (location, size and involvement with dispensing or training). They were recruited from four primary care trusts across the East of England (Cambridge, Luton, Bedford and Peterborough). Each GP conducted two consultations in their practice (one with each simulated patient), furnished with the results of appropriate medical investigations for the simulated patient. The purpose of the consultation was, from the perspective of GP and patient, to discuss the possibility of starting statin medication. This generated a total of 46 recorded consultations. For this study, we excluded videos from two GPs: one had since become a trained GP GCRS

evaluator, while the videos for the second were damaged (see online supplementary appendix 1 figure S1). This left 42 videoed consultations for assessment. All GPs gave their written consent for the re-use of their videos.

## Global Consultation Rating Scale

The GCRS covers 12 domains from 'initiating the session' to 'closure' (see online supplementary appendix 3 for the full scale). Guidance is given within the text of the scale as to the nature of the skills that are assessed within each individual domain, which is given a score as follows: Not applicable (not scored)

0. Not done/poor
1. Adequate
2. Good

The use of a three-point scale, while narrow, (1) enables a clear focus on identifying the likely need for targeted training in that area and (2) reflects the need for a simple and easy-to-use scale suitable for use while observing a consultation. A total consultation score between 0 and 24 is obtained by summing the scores from the 12 domains. In the case where a domain is considered to be not applicable, scores are renormalised to be out of 24, for example, a score of 12 out of 22 would become a score of 13.1 ( $=12 \times 24 / 22$ ) out of 24 (NB: this was not required in this study).

## GP raters

We recruited six GP raters experienced in teaching and assessing communication skills using the Calgary-Cambridge consultation guide within the School of Clinical Medicine, University of Cambridge. All attended a 2 h training session on the use of GCRS with JS, which included a specially created training video of consultations for evaluation. In training, particular attention was paid to the differences between 'good', 'adequate' and 'poor' communication behaviours, guided by the criterion referenced norms established by the Calgary-Cambridge guide. The aim was to establish a shared understanding of expected standards of behaviour across each domain.<sup>29</sup> Following training, each evaluator rated 28 videos. These were randomly assigned and provided in a random order for rating. Randomisation was performed with maximum cross over between raters to allow study of possible order effects (see online supplementary appendix for further details).

GP raters were requested to complete evaluations within 1 month of collecting the videos and were paid for their time. On receipt of ratings some missing domain scores were noted (19 of 2184, 0.87%). The five raters who had missed scores watched the corresponding videos again and filled in the missing sections only. Double data entry was conducted (NE, GA) for all ratings. For the four scores (0.20%), in which there was inconsistency, the original score sheets were consulted to obtain the correct score.

### Statistical analysis

The overall aim of this work was to estimate the statistical reliability of GCRS as a tool to assess consultations or doctors. Statistical reliability is an index of how well better performance can be distinguished from worse performance, and estimates how much of the variation in scores is due to true variation in performance rather than to noise due to different raters rating the same consultation differently. A reliability of 1 indicates that all the variation in measured scores is due to true variation in performance, that is, that scores are perfectly reliable. A reliability of 0 indicates that all the variation in measured scores is due to statistical noise. Between these two extremes, a reliability of 0.8 is generally considered the minimum required for most applications.<sup>30</sup>

Does a fixed difference between scores in GCRS have the same meaning at all levels of performance?

One of the key assumptions made when calculating reliability is that measurement errors are independent of the true values. When this is not true a single reliability value cannot apply to all scores. Another way of thinking of this is that we require a fixed difference between two scores (eg, a two point difference) to have the same distinguishing quality across the full range of scores. For this to be true, the variability in raters' scores of the same consultation must be the same at all levels of performance. We checked this by plotting the SD of ratings for each consultation against the mean score for that consultation (a variation on the standard Bland-Altman plot, allowing for more than two ratings per consultation). We found that the variance was not the same across all mean scores, implying that, for raw scores, a fixed difference does not have the same meaning at all levels of performance. We, therefore, sought a transformation to stabilise the variance across all mean scores. The transformed data were used for all further analysis.

What is the reliability of GCRS for assessing single consultations?

Our experimental setup allowed us to distinguish between three different sources of variance:

1. differing performance between doctors
2. differing performance of the same doctor between consultations, and
3. differing evaluator scores of the same consultation

In order to calculate the crude reliability, we fitted a three-level linear regression model to reflect this, with no fixed effects and with random intercepts for consultation and doctor (ie, rating nested within consultation further nested within doctor). From such a model we can estimate the reliability that would be achieved for assessing single consultations with different numbers of raters (see online supplementary appendix). The same analysis was performed on the scores for each of the individual domain of GCRS.

What is the reliability of GCRS in assessing individual doctors' performance across a number of consultations?

Using the same approach, we can also estimate the reliability of GCRS for assessing doctor's performance using different numbers of raters to assess each doctor, and using different numbers of consultations per doctor (see online supplementary appendix).

Are some raters more generous than others in their assessments of consultations?

In order to establish whether there were systematic biases between the scores given by different raters, we augmented the model described above with fixed effects for raters. If present, biases between raters will increase the variation in scores, and in turn reduce the reliability of scores. The systematic biases between raters could be accounted for, and we estimated adjusted reliabilities after doing so.

Does the order in which a consultation is rated affect the score?

Finally, to investigate possible order effects we included the order of rating in the above model. To account for non-linear effects we used a restricted cubic spline with three knots. We excluded data from one evaluator in this analysis because they had not rated the consultations in the order requested.

CIs on all estimates were calculated using bias corrected bootstrapping with 1000 repetitions and resampling at the doctor level.

The approach outlined above falls somewhere between classical reliability studies in which only one source of variance is identified (eg, inter-rater reliability) and a generalisability theory approach.<sup>31</sup> However, due to the limited data available we feel the approach taken is the most appropriate, and further it allows a more nuanced investigation of order effects considering non-linear functions.

Statistical analysis was conducted using Stata V.11.2.

### RESULTS

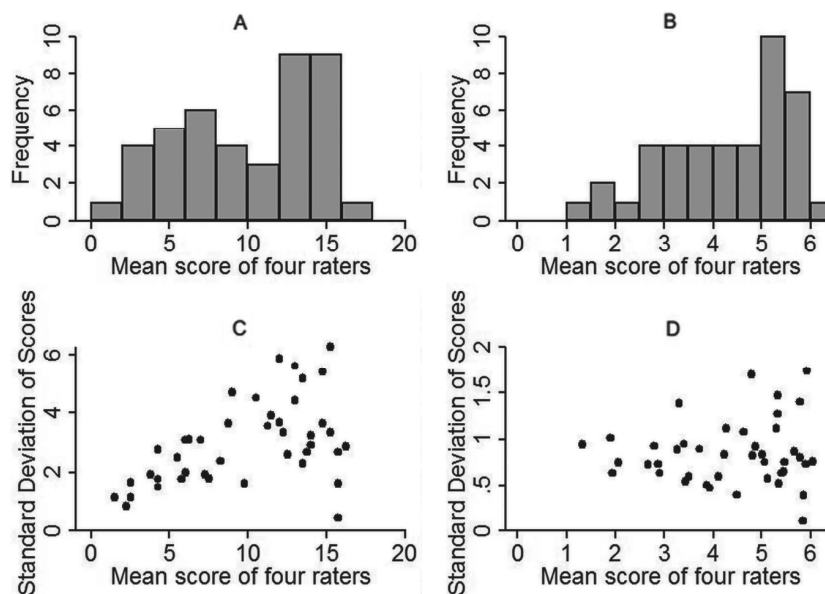
The distribution of mean scores for the 42 consultations assessed (untransformed on a 0–24 scale) is shown in figure 1A. The highest mean consultation score was 16.25 of 24 and the lowest 1.5.

Does a fixed difference in GCRS have the same meaning at all levels of performance?

Figure 1C shows the Bland-Altman type plot for the untransformed data. There was a clear trend of increasing SD of scores for each consultation with increasing mean score. This implies that there was a higher degree of agreement between raters at low scores than at the moderate scores (10–14) which form the upper end of our data set. We found that a transformation based on the logit function performed reasonably well at stabilising the variance (see online supplementary appendix



**Figure 1** Histograms showing the distribution of mean consultation scores on the native (possible values 0 to 24) scale (A) and transformed (possible values 0 to 10) scale (B). Bland-Altman plot of consultation ratings shown on the native scale (C) and transformed scale (D).



for details and lookup table). The transformation has been constructed such that the transformed scores lie between 0 and 10. The distribution of the transformed scores is shown in figure 1B.

The resulting Bland-Altman plot of transformed data is shown in figure 1D in which there is little indication of a trend (note that the increase in spread of SDs is due to the possible values available and is not considered to be a major issue). All further results relate to the transformed data.

What is the reliability of GCRS in assessing single consultations, and in assessing individual doctors' performance?

The SDs for the three sources of variation estimated from the crude mixed model (with no adjustment for rater bias) are shown in table 1. The largest SD was that for between doctors, implying that this is where the largest variation is seen. The SD of scores of the same consultation by different raters was slightly smaller than that attributed to between doctors' performance. Finally, the estimates suggested that variation at the consultation level within individual doctors was essentially zero ( $SD=1.03 \times 10^{-9}$ ). This finding is likely to be a function of our dataset. We do not present any reliability estimates for rating doctors here, and outline the reasons for this

in the discussion. The reliability estimates for rating consultations for different numbers of raters are shown in table 2. In the crude model, the commonly used reliability thresholds of 0.7 (modest), 0.8 (acceptable) and 0.9 (excellent) were achieved using two, three and seven raters, respectively.<sup>30</sup> With four raters, as used in this study, we achieved a reliability of 0.85 (95% CI 0.61 to 0.88). Details of the distribution of scores and the reliabilities of individual domains are available in online supplementary appendix figure S2 and online supplementary appendix table S2. These indicate that four raters would be sufficient to provide a broad indication of domains where a doctor may have some performance issues.

Are some raters more generous than others in their assessments of consultations?

When we allowed for systematic bias between raters in our model we found that such bias was present (table 3). On an average, a difference of 1.65 (on the 0–10 scale for transformed data) was seen between the least and most generous raters. By adjusting for evaluator bias we increased reliability somewhat (table 2), and the number of raters needed to reach the 0.7, 0.8 and 0.9 thresholds became two, three and five, respectively.

**Table 1** SDs estimated for the three sources of variation from a crude model and one adjusting for systematic bias between raters

Source of variation	SD	
	Crude model	Model adjusted for evaluator bias
Between doctors	1.21 (0.87, 1.38)	1.18 (0.87, 1.33)
Within doctors and between consultations	$1.03 \times 10^{-9}$ ( $7.25 \times 10^{-13}$ , $1.95 \times 10^{-9}$ )	0.14 (0.00, 0.15)
Within consultations and between raters	1.03 (0.96, 1.16)	0.88 (0.82, 1.01)

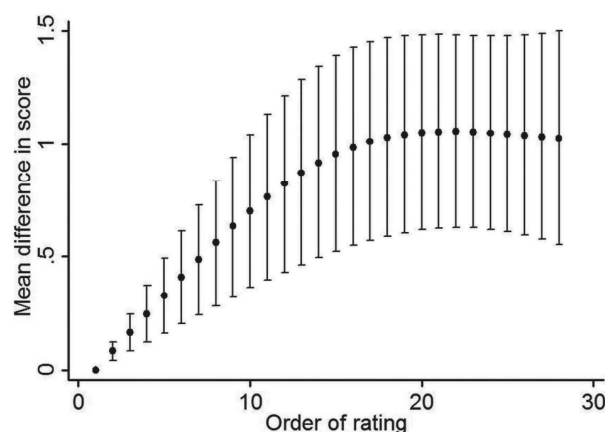
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**Table 2** Crude and adjusted reliability for evaluating consultations for different numbers of raters using GCRS (transformed 0–10 data)

Number of raters	Crude reliability* (95% CI)	Reliability adjusted for evaluator bias* (95% CI)
1	0.58 (0.28 to 0.66)	0.65 (0.36 to 0.71)
2	0.73 (0.44 to 0.79)	0.78 (0.53 to 0.83)
3	0.80 (0.54 to 0.85)	0.85 (0.63 to 0.88)
4	0.85 (0.61 to 0.88)	0.88 (0.69 to 0.91)
5	0.87 (0.66 to 0.91)	0.90 (0.74 to 0.93)
6	0.89 (0.70 to 0.92)	0.92 (0.77 to 0.94)
7	0.91 (0.73 to 0.93)	0.93 (0.80 to 0.95)
8	0.92 (0.76 to 0.94)	0.94 (0.82 to 0.95)
9	0.93 (0.78 to 0.95)	0.94 (0.84 to 0.96)
10	0.93 (0.80 to 0.95)	0.95 (0.85 to 0.96)

\*Calculated from the estimated SDs shown in table 1. GCRS, Global Consultation Rating Scale.



**Figure 2** The effect of order of rating on transformed scores compared with the first rating performed. Dots indicate point estimates and bars show 95% CIs.

Does the order in which a consultation is rated affect the score?

Finally, we found evidence of considerable order effects, with raters giving higher scores, on average, as they progressed through the rating of consultations (figure 2). It appears that raters' scoring levelled out after performing around 15–20 ratings. Later consultations received, on average, scores more than one point higher on the 0–10 scale.

## DISCUSSION

GCRS shows good reliability (>0.8) with three raters assessing each consultation, and modest reliability (>0.7) with two raters. Overall, consultations received low-to-moderate scores. This reflects previous findings with simulated patients, where it has been seen that participating doctors only attain about 40–60% of the guidelines or standards used for evaluation.<sup>32</sup> GCRS is designed to assess overall communication effectiveness of the entire doctor–patient consultation, encapsulating the quality of the interaction from the opening moments, through the gathering of information, provision of information, achieving shared understanding and shared decision-making, through to closure. It is a performance-based assessment (assessing what doctors

actually do in professional practice) rather than a competence-based assessment (assessing what doctors can do in controlled representations of professional practice).<sup>33</sup> It is additionally a criterion-referenced measure; GCRS training course highlights the importance of assessing performance against the 'gold standard' outlined in the Calgary-Cambridge guide.

While GCRS was devised as a global assessment, doctors may be interested in knowing their performance in particular domains in order to most efficiently target training. For individual GCRS domains, reliability was broadly acceptable with four raters. Low reliability for two particular domains—non-verbal communication and closure—may be attributable to small between-consultation variance rather than to raters disagreeing with each other on these areas. There are two possible explanations: either that raters find it difficult to distinguish differences in doctors' behaviours on these items (reflecting inadequate training for raters in how to assess these domains, or challenges in capturing, eg, non-verbal behaviour) or that doctors perform comparably across consultations and compared with each other on these two domains, prompting raters to award consistently similar scores.

We found that a fixed difference between scores in GCRS did not have the same meaning at all levels of performance: untransformed scores (on a scale of 0 to 24) showed a higher degree of agreement between raters at low scores than at moderate scores. For this reason, analyses were performed on transformed scores. This has implications for the most suitable score to feedback to participants if, for example, GCRS is to be used in a training situation. Transformed scores may be intuitively more difficult for participants to understand, and we need to undertake further work on the acceptability of using transformed scores in assessments of an individual doctors' performance, and how best to calculate and present transformed scores for doctors and trainers.

**Table 3** Estimated biases between raters using GCRS (transformed 0–10 data)

Evaluator	Mean difference (95% CI)
1	Reference
2	−0.25 (−0.57 to 0.13)
3	−0.68 (−1.20 to −0.18)
4	0.97 (0.66 to 1.33)
5	−0.25 (−0.76 to 0.31)
6	0.49 (0.04 to 0.96)

GCRS, Global Consultation Rating Scale.



While we found good reliability of GCRS in assessing the communication quality of individual consultations, comparison with existing instruments is difficult due to limited published psychometric data on assessing consultation (rather than doctor) quality. Interconsultation doctor reliability has been evaluated using the Four Habits Coding Scheme over 13 consultations (reliability of 0.72 with two raters),<sup>34</sup> and using the Liv-MAAS over nine consultations (reliability of 0.78 with three raters).<sup>35</sup> Evaluating the reliability of GCRS for assessing performance of individual doctors using different numbers of consultations will require more consultations per doctor, probably with greater subject variety, than we had in our dataset. We hope that further work on GCRS will enable us to estimate this in future.

We found consistent differences in scores assigned to consultations by the most and least generous raters. The Hawk/Dove phenomenon is well documented across a wide range of performance assessments, and can be addressed through training, through the use of more than one rater and through the use of post hoc statistical techniques.<sup>36</sup> All of these were employed in this study, and our finding of such variation highlights the importance of using pre-evaluation and postevaluation approaches in monitoring and acting upon differences between raters.<sup>37</sup>

We found evidence of considerable order effects. The use of multiple raters rating consultations in random order will tend to reduce order effects: sometimes a consultation will be rated early by an evaluator, and sometimes late; thus different orders for different raters average out. We have not been able to find other examples of the examination of this in GP consultation evaluation, but as previously stated, the influence of the sequential presentation of information on subsequent assessments of this information is a well-known phenomenon in the psychological literature.<sup>26</sup> Again, this is something which requires further work to assess how GCRS will perform in training situations.

The current study has a number of limitations. We included only a small number of GPs whose consultations had been recorded, derived from an earlier study, and only two similar scenarios per GP. These standardised scenarios do not reflect real-world consultations of variable nature and content, and we believe these are the reasons why we find little variation between consultations of the same doctor. We could not, therefore, assess how raters responded to different contexts: this is the focus of our next stage of work.

There are various sources of possible bias we did not examine due to sample size limitations. For example, contrast effect bias may be important in influencing rater behaviour, where, for example, viewing a good consultation after a series of poor consultations may lead to a substantial leap in scores assigned due to the contrast between them.

Feedback from raters showed that the assessment of consultations required significant concentration. Average consultation length was around 15 min: viewing each

consultation and completing the rating scale means each evaluation can take around 20 min.

## CONCLUSIONS

GCRS has good reliability (>0.8) for rating consultations if three raters are used. Systematic differences were observed between raters: adjusting for these further improves reliability of the scale. We are currently developing the scale further by assessing a large sample of consultations in a real-world setting. This will enable a more detailed examination of the ability of the scale to assess performance between consultations of the same doctor. Once further psychometric evaluation is completed, we envisage that GCRS has the capacity to provide a robust yet practical assessment tool for the evaluation of communication skills in everyday practice, linked to the Calgary-Cambridge training approach to target identified areas for improvement.

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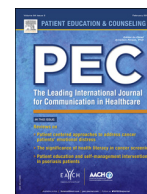


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## The reliability of a modified Kalamazoo Consensus Statement Checklist for assessing the communication skills of multidisciplinary clinicians in the simulated environment

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## ABSTRACT

**Objective:** With increased recognition of the importance of sound communication skills and communication skills education, reliable assessment tools are essential. This study reports on the psychometric properties of an assessment tool based on the Kalamazoo Consensus Statement Essential Elements Communication Checklist.

**Methods:** The Gap-Kalamazoo Communication Skills Assessment Form (GKCSAF), a modified version of an existing communication skills assessment tool, the Kalamazoo Essential Elements Communication Checklist-Adapted, was used to assess learners in a multidisciplinary, simulation-based communication skills educational program using multiple raters. 118 simulated conversations were available for analysis. Internal consistency and inter-rater reliability were determined by calculating a Cronbach's alpha score and intra-class correlation coefficients (ICC), respectively.

**Results:** The GKCSAF demonstrated high internal consistency with a Cronbach's alpha score of 0.844 (faculty raters) and 0.880 (peer observer raters), and high inter-rater reliability with an ICC of 0.830 (faculty raters) and 0.89 (peer observer raters).

**Conclusion:** The Gap-Kalamazoo Communication Skills Assessment Form is a reliable method of assessing the communication skills of multidisciplinary learners using multi-rater methods within the learning environment.

**Practice implications:** The Gap-Kalamazoo Communication Skills Assessment Form can be used by educational programs that wish to implement a reliable assessment and feedback system for a variety of learners.

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### 1. Introduction

Sound interpersonal and communication skills are critical to the provision of quality healthcare. Effective communication with patients, families and physicians has been shown to enhance coping, mitigate grief, improve adherence to treatment, alter perceptions of care and reduce medical errors and litigation [1–6]. The National Board of Medical Examiners (NBME), Association of American Medical Colleges (AAMC), Institute of Medicine, and Accreditation Council on Graduate Medical Education (ACGME)

have suitably placed a priority on the teaching and assessment of interpersonal and communication skills in undergraduate and graduate medical education [6–10]. Consequently, in the United States, achieving competency in communication has become a factor for promotion, graduation and licensure [7–9]. Teaching and assessing communication skills remains a complex and historically under-represented component of medical education [10,11]. Fortunately, increased awareness of the importance of communication and relationships in healthcare, and more emphasis on the importance of communication skills training in medical education, has led to an ever growing body of literature regarding the teaching and assessing of communication skills available to educators [10,12–17]. This article reports on the psychometric properties of an assessment tool which was derived from The Kalamazoo Consensus Statement [18], an exemplar in the field of medical communication research, education and assessment.

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The Kalamazoo Consensus Statement was developed in 1999 by 21 North American leaders from the fields of medical education and communication [18]. Their intent was to delineate a list of elements essential to physician–patient communication for the purpose of facilitating the development, implementation and evaluation of communication curricula [18]. The result was a list of seven “essential elements,” or communication tasks, that define effective physician–patient communication. This consensus statement has since served as a framework for the development of numerous educational programs [10,15,19–23].

In subsequent years the same group met to create the Kalamazoo Essential Elements Communication Checklist (KEECC), an assessment tool for the purpose of rating learners' competency across the seven essential elements of the Kalamazoo Consensus Statement [10]. The essential elements, or competencies (Builds the Relationship, Opens the Discussion, Gathers Information, Understands the Patient's and Family's Perspective, Shares Information, Reaches Agreement, and Provides Closure), are rated using a categorical 4-option scale across 24 sub-competencies. This tool has applicability to all levels of training and various settings [10]. Two additional iterations of the KEECC, the Kalamazoo Essential Elements Communication Checklist-Adapted (KEECC-A) [10] and the Gap-Kalamazoo Communication Skills Assessment Form (GKCSAF) [10] have been published. The GKCSAF has been adapted for multi-rater use, a powerful method for assessing communication skills that enhances self-insight [11,24]. In combination, these three tools have been used in undergraduate and graduate medical education and healthcare education programs nationally and internationally [10,11,24,25].

Simulation, either through the use of role-play or standardized patients, is an increasingly common and effective educational modality for use in communication skills education [3,13,15]. With the growth of simulation-based training comes the need for reliable assessment tools for use in the simulated environment. While psychometric data exists regarding the KEECC [9], KEECC-A [25] and GKCSAF [11], to our knowledge no study has evaluated inter-rater reliability among the communication elements of the Kalamazoo Tools, nor has there been a psychometric analysis for a multidisciplinary field of learners in the simulated environment.

The objective of this paper, therefore, is to build on the work of previous studies, by reporting the internal consistency and inter-rater reliability of the GKCSAF when used for multi-rater assessment of multi-disciplinary learners in a simulation-based communication skills education program.

## 2. Methods

### 2.1. Tool development

Three assessment tools based on the Kalamazoo Consensus Statement have been published [10]. The original tool, the KEECC, rated learners categorically (i.e., done well, needs improvement, not done, not applicable) on seven competencies and 24 sub-competencies [10,18]. Rider and colleagues at Harvard Medical School adapted the KEECC by adding a 5-point Likert scale (1 = poor to 5 = excellent) [10]. This adapted version, the KEECC-A, allows for evaluation of the seven Kalamazoo Essential Elements on a global ratings scale and the 24 sub-competencies function as a rubric for this checklist [10]. The Likert scale can also be used to rate each competency and sub-competency. Calhoun, Rider and colleagues modified the KEECC-A to include two more communications elements, Demonstrates Empathy and Communications Accurate Information, creating the GKCSAF [10,24]. This latest Kalamazoo Consensus Statement instrument was also modified for use by multiple raters (modeled after 360° assessment tools) and includes a section for gap analysis [24]. Gap analysis is a novel application of multi-rater feedback that consists of comparing rating scores from different groups of raters, for example faculty or peer observers, with self-score of the participant or participant team [11]. This comparison of scores has been shown to enhance learner self-insight [11]. The GKCSAF contains Likert-scale, forced-choice, and free-text fields, enabling it to provide absolute and relative scores for each aspect of communication and specific comments regarding strengths and areas needing improvement. A similar version of the instrument was created for simulated patients/families using language that was assessed by Microsoft Word as suitable for a reader at the United States 6th grade reading level, which roughly translates to a reading level appropriate for a 10–12 year old (Table 1).

**Table 1**  
Description of the Kalamazoo Consensus Statement assessment instruments.<sup>a</sup>

Kalamazoo instrument	Data type	Instrument description	Psychometric studies
Kalamazoo Essential Elements Communication Checklist	Categorical ratings: Done well Needs improvement Not done Not applicable	Includes the Kalamazoo Consensus Statement 7 core communication competencies and 24 sub-competencies	Schirmer JM, Mauksch L, Lang F, Marvel MK, Zoppi K, Epstein RM, Brock D, Pryzbylski M. Assessing communication competence: a review of current tools. <i>Fam Med</i> 2005;37:184–92
Kalamazoo Essential Elements Communication Checklist-Adapted <sup>b</sup>	5-point Likert scale: 1 = poor to 5 = excellent	Global ratings on the 7 core competencies Second version with ratings on 7 core and 24 sub-competencies	Joyce BL, Steenbergh T, Scher E. Use of the Kalamazoo Essential Elements Communication Checklist (Adapted) in an institutional interpersonal and communication skills curriculum. <i>J Grad Med Educ</i> 2010;2:165–9
Gap-Kalamazoo Communication Skills Assessment Form	Likert-scales, forced-choice and free-text fields to provide absolute and relative scores for each competency; and specific comments on strengths and areas needing improvement	Global ratings on the 7 core competencies and 2 additional competencies: Demonstrates Empathy, and Communicates Accurate Information Versions: • Clinician/Faculty (also used by Peer Facilitators) • Self-assessment • Patient/Family (6th grade reading level)	Calhoun AW, Rider EA, Meyer EC, Lamiani G, Truog RD. Assessment of communication skills and self-appraisal in the simulated environment: feasibility of multi-rater feedback with gap analysis. <i>Simul Healthc</i> 2009;4:22–9

<sup>a</sup> The instruments are published in: Rider EA, Nawotniak RH. A practical guide to teaching and assessing the ACGME core competencies, 2nd ed. Marblehead, MA: HCPro Inc.; 2010.

<sup>b</sup> To preserve research integrity, we recommend using the authentic versions of the Kalamazoo instruments. The version of the GKCSAF used in this study is included as an Appendix with this article.

## 2.2. Tool implementation

The GKCSAF has been used for four years to assess communication competencies of participants in the Program for the Approach the Complex Encounters (PACE). PACE is a simulation-based curriculum at the University of Louisville School of Medicine developed to enhance the skills of multidisciplinary healthcare professionals in navigating challenging communication situations [15]. PACE relies on the Kalamazoo Consensus Statement competencies as a framework for communication skills education. During a PACE session, after a brief discussion of communication strategies, resident/nurse (or rarely resident/chaplain) clinician teams embark on a simulated conversation with a patient family portrayed by standardized patients (SP). Clinician teams always consist of one physician and one allied health professional, however, determination of which participants simulate which conversation are left up to the participants themselves. PACE sessions are typically attended by two to three faculty members who help guide post-simulation feedback and discussion. Each simulated conversation is rated by PACE faculty members, standardized patients, peer-observers and the participants themselves in a 360° fashion using the GKCSAF.

## 2.3. Tool training

Faculty, peer observers, standardized patients and participants were not trained specifically on the use of the GKCSAF prior to this study. This was done intentionally as many assessment tools have been validated by studies in which raters were formally trained on the use of the tool in question. Extensive training, however, is not always possible given the issues of lack of free time that chronically plague busy clinical faculty, residents with duty-hours restrictions and hospital staff carrying full-time work schedules. Thus, we wanted to assess the psychometric properties of the GKCSAF in an environment that most closely reflects how we anticipate this tool will be used.

## 2.4. Scoring

The GKCSAF is composed of nine essential communication elements rated on a 5-point Likert Scale (1 = Poor, 2 = Fair, 3 = Good, 4 = Very good, 5 = Excellent). In the PACE sessions, four versions of the Gap-Kalamazoo Tool are generated for each simulated conversation, generated by the four groups of raters: a self-assessment, faculty assessment, peer observer assessment and standardized patient (SP) assessment. Competency-specific overall scores are calculated by averaging individual scores for each competency. Learners are provided a written feedback form following their PACE session, detailing cumulative assessment scores from all raters across all communication elements.

## 2.5. Statistical analysis

For the purpose of statistical analysis, faculty and peer observer ratings were used. The unit of analysis was the clinician team. To assess internal consistency, a Cronbach's alpha score was calculated for simulated conversations to provide an overall alpha for faculty and peer ratings, respectively. These groups were chosen due to the relatively consistent number of raters across all sessions, allowing for more consistent statistical assessment. In addition to this, we calculated a separate Cronbach's alpha for each faculty rater across all sessions and averaged these values to generate an additional Cronbach's alpha. This was done to assure the accuracy of the initial score, given the possibility of intra-session correlations in rating that could artificially elevate the statistic. As the same peer observers did not rate every conversation within a PACE session, we were unable to perform a separate Cronbach's alpha for peer observers in the same manner. Inter-rater reliability was analyzed using intra-class correlation coefficients (two-way random, consistency measures) (ICC). This statistic was calculated for all simulated conversations in which 3 faculty members or peer observers provided ratings. ICC's were calculated for each communication element and for the overall average score of each tool. Cronbach's alpha scores and ICCs are reported for faculty and peer observers separately. Statistics were calculated using SPSS ver 21.

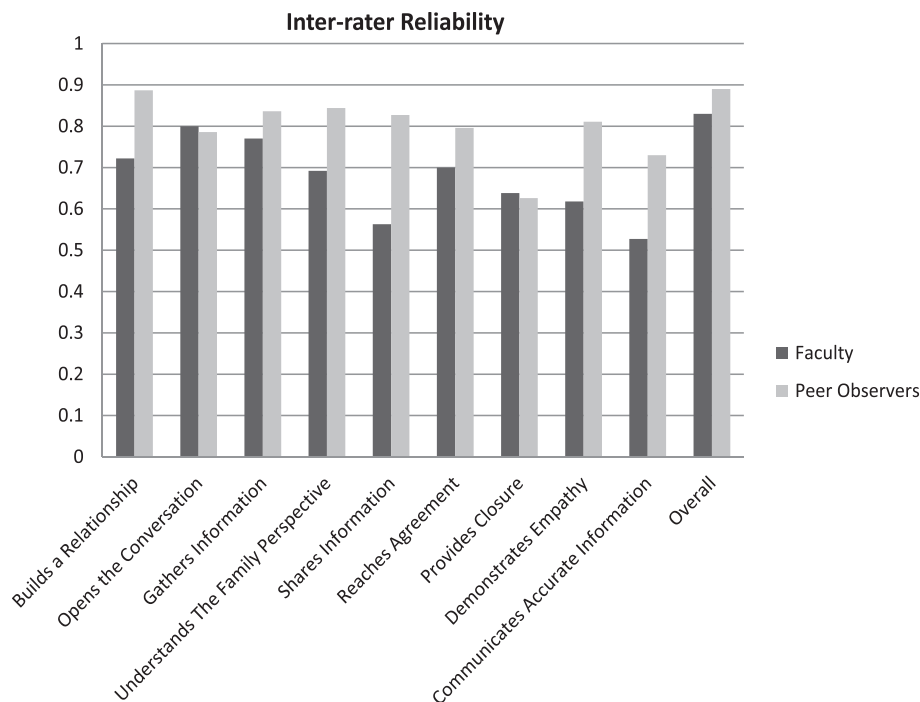


Fig. 1. Intra-class correlation coefficient scores for communication domains of the Gap-Kalamazoo Communication Skills Assessment Form for faculty and peer observers.

### 3. Results

#### 3.1. Subjects

Since its inception in 2009, PACE has simulated 118 conversations for 173 participants. Participants include medical residents 2–4 years after receiving their M.D. degree (categorical pediatric and combined pediatric/internal medicine residents,  $N = 108$ ), nurses (bedside nurses, nursing administrators and nursing students,  $N = 63$ ) and hospital chaplains ( $N = 2$ ). Of those conversations, 44 had 3 faculty raters and 25 had 3 peer observer raters rendering them eligible for analysis by ICC.

#### 3.2. Tool internal consistency

There were 118 faculty rated conversations and 72 peer observer rated conversations from which to calculate a Cronbach's alpha. The Gap-Kalamazoo tool demonstrated an overall Cronbach's Alpha of 0.844 for faculty and 0.880 for peer observers. Faculty rater-specific Cronbach's alpha scores were 0.837 ( $N = 106$  of conversations used for calculation), 0.818 ( $N = 104$ ) and 0.90 ( $N = 61$ ), respectively. The overall average of the faculty rater sub-alpha scores was 0.852.

#### 3.3. Tool reliability

Faculty ICC scores ranged from 0.527 to 0.800 for each domain of communication. Among faculty, the lowest ICC's were noted for the elements of Communicates Accurate Information and Shares Information (0.527 and 0.563, respectively), while the elements with the highest ICC's were Opens the Discussion and Gathers Information (0.800 and 0.770, respectively). The overall ICC was 0.830.

Peer observer ICC scores ranged from 0.626 to 0.887 for each domain of communication. Among peer observers, only one communication domain, Provides Closure, scored  $<0.7$ . Five elements had ICCs  $>0.8$ . The overall ICC was 0.890 (Fig. 1).

### 4. Discussion and conclusion

#### 4.1. Discussion

The three published assessment tools developed from the Kalamazoo Consensus Statement (Table 1) are valuable resources for communication skills education [10]. Psychometric analysis of these tools strengthens their applicability across a variety of learning environments. A 2005 analysis of the psychometric properties of the KEECC demonstrated a Cronbach's alpha of 0.88 [9]. Previously published psychometric data analysis of the KEECC-A reported good internal consistency for a cumulative communications rating when used to evaluate medical residents during a simulated clinical encounter [25]. Good internal consistency has been previously published for the Gap-Kalamazoo Tool but was based on a small sample size of only seven learners [11]. To our knowledge no study has evaluated inter-rater reliability among the communication elements of the Kalamazoo Tools, nor has there been a psychometric analysis for a multidisciplinary field of learners. This latter consideration is of special importance, as the GKCSAF was specifically designed for a multidisciplinary, multi-rater assessment.

We designed the PACE curriculum to include multi-rater feedback. Multi-rater feedback is a holistic approach to evaluation particularly suited to communication skills training that places the learner at the center of multiple relationships including peers, patients/families and faculty [11]. By encompassing the feedback of patients/families and multi-disciplinary clinician peers, real-world validity is enhanced and more comprehensive feedback can be generated for learners [11]. Likewise, the GKCSAF is designed for multi-rater use, therefore, we chose to assess the internal

consistency and inter-rater reliability for both faculty and peer observer ratings. However, we did not generate a combined ICC value that included both groups. This was done deliberately because we expect that perceptions of skill will differ among the groups of raters. This is due to the nature of multi-rater feedback, which postulates differences in the perspective and hence content of feedback provided between disciplinary groups. If this were not case, multi-rater feedback would be unnecessary as all perceptions of skill will be the same. In support of this view, participants receive written feedback that encompasses the ratings and comments from all groups of raters, and a global general score is not provided.

#### 4.1.1. Internal consistency

The GKCSAF demonstrates good internal consistency with a Cronbach's alpha of 0.844 and 0.880 for faculty ( $N = 118$ ) and peer observer ratings ( $N = 75$ ), respectively. These scores are consistent with previously published data for earlier versions of the tool. Knowing that calculating an overall alpha carried the risk of bias, due to a potential of clustering scores for a given conversation, we calculated a sub-alpha score per randomly assigned faculty rater to ensure the overall alpha was not falsely elevated. Finding an average sub-alpha similar to the overall alpha lends credibility to the internal consistency and lessens the concern about potential bias within a conversation. As mentioned above, we were unable to perform such a sub-analysis for peer observer ratings, as peer observers changed with every given conversation and hence could not be separated in the same manner as faculty. The strength of this study is the number of conversations analyzed, at 118 for faculty, and 72 for peer observer, which is much higher than previously reported psychometric data regarding the Gap-Kalamazoo tool.

#### 4.1.2. Inter-rater reliability

For the purposes of assessing inter-rater reliability, we chose to use conversations that had 3 raters for statistical reasons. This limited our data set to 44 faculty-rated conversations and 25 peer-observer-rated conversations.

The ICC scores for faculty ratings across the nine communication elements assessed in the Gap-Kalamazoo tool ranged from 0.527 to 0.800 but demonstrated high inter-rater reliability with an overall ICC 0.830. Specifically, Communicates Accurate Information and Shares Information had relatively low ICCs of 0.527 and 0.563, respectively, Demonstrates Empathy, Provides Closure and Understands the Patient's and Family's Perspective had acceptable ICCs between 0.6 and 0.7, while the remaining four elements of Builds a Relationship, Opens the Discussion, Gathers Information, Reaches Agreement had good ICCs of  $\geq 0.7$ . It was of interest to us that certain elements of the communication checklist demonstrated higher inter-rater reliability than others. Particularly, the elements of Communicates Accurate Information and Shares Information showed the poorest inter-rater reliability. While we feel that Communicates Accurate Information and Shares Information are two important and distinct communication tasks, the lower ICCs for these two elements could represent a higher subjectivity for these elements or even a perceived redundancy or confusion regarding the essence of these tasks. This could represent a need for clarifying language within the evaluative rubric as to the true conceptual content of these elements. Of note, the overall average scores of the communication encounter demonstrated higher reliability among raters than any individual domain, conceivably indicating that general impressions of overall communication skill are preserved with the Gap-Kalamazoo tool. Hence, even if individual elements lacked agreement, there was consensus regarding the clinician teams' overall performance during the simulated conversation.

The ICC scores for peer observer ratings across the nine communication elements assessed in the Gap-Kalamazoo tool ranged from 0.626 to 0.887 with an overall inter-rater reliability of

0.890. One communication domain, Provides Closure, demonstrated acceptable inter-rater reliability with an ICC of 0.626. Three domains, Opens the Discussion, Reaches Agreement and Communicates Accurate Information had ICCs in the good range of  $\geq 0.7$  while the remaining five elements displayed excellent inter-rater reliability with ICCs  $\geq 0.8$ . Parallel to faculty ratings, the overall rating of the communication encounter demonstrated a higher ICC than any individual domain at 0.890, again suggesting that overall ratings of skill may be preserved among raters even if perceptions of skill for individual communication tasks differ.

In general, higher inter-rater reliability was demonstrated among peer observers than faculty raters. We can think of several reasons why this might exist. First, it is possible that peer observer scores tend to cluster in one direction. We also wondered whether peer observers might cluster scores in a more generally favorable manner. To test the theory that peer observers might perceive overall communication skills as better than faculty raters, we compared the average ratings among peer observer and faculty raters and found they did not differ significantly (3.93 vs. 3.98,  $p$ -value 0.54 by Mann–Whitney  $U$ ). Second, peer observers were unfamiliar with the GKCSAF prior to completing the assessment tool and this could have led to differences in perception of the communication elements, as opposed to faculty who had prior experience with the tool.

#### 4.1.3. Limitations

While we feel this study shows the Gap-Kalamazoo tool a useful and reliable instrument for assessing learners participating in a communication skills curriculum, there are several limitations that bear discussion.

First, generalizability theory is an alternative method to assess the reliability of assessment tools and is felt to be superior to more traditional means of determining reliability as it can detect multiple sources of error [26]. A generalizability study, had we been able to perform it, would have yielded more information than our current approach. Unfortunately, the structure of our dataset rendered a generalizability study impossible.

Second, this tool is intended for use by multiple raters but we were unable to analyze reliability within all groups of raters. Although ratings are obtained from the four groups, faculty, peer observers, standardized patients and self/participants, we only had sufficient data to analyze faculty and peer observers. To calculate inter-rater reliability we chose to use conversations that were rated by three individuals. Unfortunately, we had no conversations in which more than two standardized patients or participants ("self-scores") rated a conversation so we were unable to assess the psychometric properties within these groups of raters. A study in which reliability was analyzed with all groups of raters would certainly be a stronger study but we did not have the data to perform such an analysis. We still feel the tool demonstrated reasonable reliability within the two groups of raters mentioned above, supporting its use in a multi-rater fashion. Additionally, due to the variability in peer observer ratings, we were unable to perform a "sub-alpha" to confirm the accuracy of the Cronbach's alpha score for peer observer ratings as we were for faculty ratings. It is possible, then, that the reported Cronbach's alpha score of 0.880 for peer observer ratings is falsely elevated.

Third, other than the theories briefly mentioned above, it is unclear to us why some elements of the tool performed well while others showed generally poor inter-rater reliability, particularly among faculty members. Unfortunately, we have not had the opportunity to discuss the use of the tool among faculty raters, as doing so may elucidate why it was easier to reach agreement among certain elements than others.

Last, and most important, a significant limitation of this study is the fact that post-simulation debriefing occurred prior to

completion of the assessment tool. Results regarding inter-rater reliability should be viewed with caution, knowing that post-simulation discussion likely led to some normalization of the data. The order of debriefing in relation to tool completion was a conscious decision from the outset of curriculum development in an effort to create and preserve a learning atmosphere. Simulating complicated, emotionally charged conversations while being viewed by others is a vulnerable position for learners, and we strive to create a safe learning environment that promotes an atmosphere of self-discovery. The GKCSAF takes approximately 10–15 min to complete, time we felt, would create a disruption of the learning environment and place an unwanted emphasis on evaluation and assessment for our learners. We designed the curriculum not for the purposes of validating the assessment tool but with the goal of creating an effective communication skills curriculum. In doing so, we placed a higher priority on the learning environment than the rigors of the study presented here. We realize that this was a judgment call and whether or not completing the assessment prior to debriefing would affect learners as we purport remains to be seen. We do contend that holding the debriefing prior to completing the assessment tool led to less normalization of the data than one might think due to the nature of the debriefing session. The debriefing component of this curriculum relies heavily on participant self-directed learning and discovery using recorded simulations for playback and review. Feedback and discussion is directed using frame-by-frame analysis of the conversations, led by the self-insights of the participants and observers. Participants and peer observers are unfamiliar with the GKCSAF. There is no mention of, or reference to, the Kalamazoo Essential Elements framework during the discussion. To summarize, the possibility exists that influence on raters from the debriefing session led to inflation of the inter-rater reliability of the GKCSAF. Given that the environment in which we use the tool is similar to how it will likely be used in practice, we still feel the GKCSAF is a useful tool, viewed within the constraints mentioned above.

#### 4.2. Conclusions

The importance of developing sound communication skills among healthcare professionals and the greater emphasis on communication skills education in undergraduate and graduate medical education makes reliable assessment methodologies essential. The Gap-Kalamazoo Communication Skills Assessment Form is linked to an accepted theoretic framework, builds on studies utilizing earlier versions of the Kalamazoo assessment tools, and has been demonstrated to have good psychometric reliability, and therefore begins to meet this important need. Further research exploring the inter-rater reliability among all groups of raters, completion of the assessment tool prior to debriefing, and use of generalizability theory would further define the usefulness of this tool.

#### 4.3. Practice implications

Despite the limitations mentioned above, the Gap-Kalamazoo Communication Skills Assessment Form can be used by educational programs that wish to implement a reliable assessment and feedback system for a variety of multidisciplinary learners.

*Note:* A different tool with different contents, but also titled the Kalamazoo Essential Elements Communication Checklist-Adapted, is found on the Internet. To preserve research integrity, we recommend using the authentic, copyrighted, validated version. Questions regarding use of the GKCSAF tool can be directed to [aaron.calhoun@louisville.edu](mailto:aaron.calhoun@louisville.edu) or [elizabeth\\_rider@hms.harvard.edu](mailto:elizabeth_rider@hms.harvard.edu) (member, Kalamazoo Consensus Statement group).

## Appendix

## Gap-Kalamazoo Communication Skills Assessment Form\* – Faculty/Peer Assessment

Date:	Your Name:	Your Title:
-------	------------	-------------

Title of Case:	Title of Conversation:
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How well did the participant(s) do the following (please select one):

	1 Poor	2 Fair	3 Good	4 Very Good	5 Excellent
<b>A: Builds a relationship (includes the following):</b> <ul style="list-style-type: none"> <li>• Greets and shows interest in the patient's family</li> <li>• Uses words that show care and concern throughout the interview</li> <li>• Uses tone, pace, eye contact, and posture that show care and concern</li> <li>• Responds explicitly to patient and family statements about ideas and feelings</li> </ul>					
<b>B: Opens the discussion (includes the following):</b> <ul style="list-style-type: none"> <li>• Allows patient and family to complete opening statement without interruption</li> <li>• Asks "is there anything else?" to elicit full set of concerns</li> <li>• Explains and/or negotiates an agenda for the visit</li> </ul>					
<b>C: Gathers information (includes the following):</b> <ul style="list-style-type: none"> <li>• Addresses patient and family statements using open-ended questions</li> <li>• Clarifies details as necessary with more specific or "yes/no" questions</li> <li>• Summarizes and gives family opportunity to correct or add information</li> <li>• Transitions effectively to additional questions</li> </ul>					
<b>D: Understands the patient's and families perspective (includes the following):</b> <ul style="list-style-type: none"> <li>• Asks about life events, circumstances, other people that might affect health</li> <li>• Elicits patient's and family's beliefs, concerns, and expectations about illness and treatment</li> </ul>					
<b>E: Shares information (includes the following):</b> <ul style="list-style-type: none"> <li>• Assesses patient's/family's understanding of problems and desire for more info</li> <li>• Explains using words that family can understand</li> <li>• Asks if family has any more questions</li> </ul>					
<b>F: Reaches agreement (includes the following):</b> <ul style="list-style-type: none"> <li>• Includes family in choices and decisions to the extent they desire</li> <li>• Checks for mutual understanding of diagnostic and/or treatment plans</li> <li>• Asks about acceptability of diagnostic and/or treatment plans</li> <li>• Identifies additional resources as appropriate</li> </ul>					
<b>G: Provides closure (includes the following):</b> <ul style="list-style-type: none"> <li>• Asks if patient and family have questions, concerns or other issues</li> <li>• Summarizes</li> <li>• Clarifies future time when progress will again be discussed</li> <li>• Provides appropriate contact information if interim questions arise</li> <li>• Acknowledges patient and family, and closes interview</li> </ul>					
<b>H. Demonstrates Empathy (includes the following):</b> <ul style="list-style-type: none"> <li>• Clinician's demeanor is appropriate to the nature of the conversations</li> <li>• Shows compassion and concerns</li> <li>• Identifies/labels/validates patient's and family's emotional responses</li> <li>• Responds appropriately to patients and family's emotional cues</li> </ul>					
<b>I: Communicates accurate information (includes the following):</b> <ul style="list-style-type: none"> <li>• Accurately conveys the relative seriousness of the patient's condition</li> <li>• Takes other participating clinician's input into account</li> <li>• Clearly conveys expected disease course</li> <li>• Clearly presents and explains options for future care</li> <li>• Gives enough clear information to empower decision making</li> </ul>					

\*Adapted from: Essential Elements: The Communication Checklist, © 2001 Kalamazoo Consensus Statement Group, and from: Rider EA. Interpersonal and Communication Skills. In: Rider EA, Nawotniak RH. *A Practical Guide to Teaching and Assessing the ACGME Core Competencies, 2nd edition.* Marblehead, MA: HCPro, Inc., 2010. © 2010 HCPro, Inc. Used with permission. Contacts: Elizabeth Rider, MSW, MD - elizabeth\_rider@hms.harvard.edu (member, Kalamazoo Consensus Statement Group) and Aaron Calhoun, MD - aaron.calhoun@louisville.edu (PERCS Program)

**What did the participant(s) do best? (Please pick three choices)**

- 
- Builds a Relationship
  - Opens the Discussion
  - Gathers Information
  - Understands the Patient's and Family's Perspective
  - Shares Information
  - Reaches Agreement
  - Provides Closure
  - Demonstrates Empathy
  - Communicates Accurate Information
- 

**Why did you choose those particular answers?****In which domains could the participant(s) improve? (Please pick three choices)**

- 
- Builds a Relationship
  - Opens the Discussion
  - Gathers Information
  - Understands the Patient's and Family's Perspective
  - Shares Information
  - Reaches Agreement
  - Provides Closure
  - Demonstrates Empathy
  - Communicates Accurate Information
- 

**What could have been done better?**

\*Adapted from: Essential Elements: The Communication Checklist, © 2001 Kalamazoo Consensus Statement Group, and from: Rider EA. Interpersonal and Communication Skills. In: Rider EA, Nawotniak RH. *A Practical Guide to Teaching and Assessing the ACGME Core Competencies, 2nd edition*. Marblehead, MA: HCPro, Inc., 2010. © 2010 HCPro, Inc. Used with permission. Contacts: Elizabeth Rider, MSW, MD - elizabeth\_rider@hms.harvard.edu (member, Kalamazoo Consensus Statement Group) and Aaron Calhoun, MD - aaron.calhoun@louisville.edu (PERCS Program)

**Conflict of interest**

None.

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ORIGINAL PAPER

## Evaluating the effectiveness of rating instruments for a communication skills assessment of medical residents

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**Abstract** The investigators used evidence based on response processes to evaluate and improve the validity of scores on the Patient-Centered Communication and Interpersonal Skills (CIS) Scale for the assessment of residents' communication competence. The investigators retrospectively analyzed the communication skills ratings of 68 residents at the University of Illinois at Chicago (UIC). Each resident encountered six standardized patients (SPs) portraying six cases. SPs rated the performance of each resident using the CIS Scale—an 18-item rating instrument asking for level of agreement on a 5-category scale. A many-faceted Rasch measurement model was used to determine how effectively each item and scale on the rating instrument performed. The analyses revealed that items were too easy for the residents. The SPs underutilized the lowest rating category, making the scale function as a 4-category rating scale. Some SPs were inconsistent when assigning ratings in the middle categories. The investigators modified the rating instrument based on the findings, creating the Revised UIC Communication and Interpersonal Skills (RUCIS) Scale—a 13-item rating instrument that employs a 4-category behaviorally anchored rating scale for each item. The investigators implemented the RUCIS Scale in a subsequent communication skills OSCE for 85 residents. The analyses revealed that the RUCIS Scale functioned more effectively than the CIS Scale in several respects (e.g., a more uniform distribution of ratings across categories, and better fit of the items to the measurement model). However, SPs still rarely assigned ratings in the lowest rating category of each scale.

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**Keywords** Validity · Rating scale · Communication skills · Many-faceted Rasch measurement · OSCE

## Introduction

Communication and interpersonal skills are one of the six core competencies for which residency programs have to demonstrate training outcomes (Accreditation Council for Graduate Medical Education 1999). An assessment of residents' communication skills that can provide valid inferences about their ability to exchange information and ally with patients requires an observed interaction with patients. The Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) recommend using an assessment format that asks residents to interact with standardized patients (SPs) in an Objective Structured Clinical Examination (OSCE) as the most desirable approach for communication skills assessment (Bashook and Swing 2000).

The rating instrument that a standardized patient uses to record his/her observations of a resident's performance during a communication skills OSCE plays a critical role in providing valid inferences from an assessment. A rating instrument not only guides the observation but also dictates the scoring of the performance of individual residents. Several rating instruments for the assessment of medical communication skills by SPs in OSCE settings have been developed and validated, including the Interpersonal and Communication Skills Checklist (Cohen et al. 1996), the Interpersonal Skills Rating Form (Schnabl et al. 1991), the Arizona Clinical Interview Rating Scale (Stillman et al. 1976, 1986), the Brown University Interpersonal Skill Evaluation (Burchard and Rowland-Morin 1990), the SEGUE Framework (Makoul 2001), the Liverpool Communication Skills Assessment Scale (LCSAS) (Humphris 2002; Humphris and Kaney 2001), and the Patient-Centered Communication and Interpersonal Skills (CIS) Scale (Yudkowsky et al. 2004, 2006).

Despite the many available rating instruments for communication skills assessment in OSCE settings, choosing an appropriate instrument to score residents' performance in a communication skills OSCE is not an easy task. Validity evidence that supports the use of scores obtained from these rating instruments is quite limited. Researchers conducting validity studies of these instruments have focused mainly on reporting internal consistency reliability, inter-rater reliability, and correlations of scores with measures of other variables. According to the *Standards for Educational and Psychological Testing* (American Educational Research Association et al. 1999), such validity research only provides evidence based on internal structure and relations to other variables, leaving out evidence based on test content, response processes, and consequences.

In this study, we evaluated validity evidence related to the use of one of the existing communication skills OSCE rating instruments—the Patient-Centered Communication and Interpersonal Skills (CIS) Scale. We focused on evidence based on response processes, a source of validity evidence that test score users often overlook. In the context of a communication skills OSCE, the validity evidence based on response processes refers to the evaluation of the extent to which the SPs apply rating criteria to rate the residents' performance in a manner that is consistent with the intended interpretation and uses of scores (American Educational Research Association et al. 1999).

There are several approaches that researchers can use to gather validity evidence based on response processes. Researchers can collect some pieces of evidence before the OSCE

administration (e.g., documenting the rating criteria and the processes for selecting, training, and qualifying SPs). Researchers can collect other pieces of evidence at the time a SP rates the performance (e.g., engaging SPs in verbal think-aloud during the rating process, thus allowing researchers to know what SPs are thinking while deciding what rating they will assign (Heller et al. 1998)). The focus of this study was on gathering validity evidence related to response processes after an OSCE administration (i.e., when all the ratings were available to us). That is, we carried out a psychometric analysis of ratings to investigate to what extent the OSCE ratings were consistent with the intended uses of the scores. OSCE ratings are the result of the interaction between residents, cases, items (and their rating scales), and SPs. A comprehensive validity study of response processes for an OSCE would require close examination of responses related to all these components of an OSCE. In this study, we limited the scope of our analyses to response processes related to items and scales on the rating instrument. That is, we investigated the extent to which SPs used the rating instrument to rate the residents' performance in a way that was consistent with the intended uses of the scores.

This study looked at the use of the CIS Scale in the scoring of internal medicine residents' performance in communication skills OSCEs carried out at the University of Illinois at Chicago (UIC). The purposes of our study were (1) to evaluate the effectiveness of the CIS Scale in scoring the residents' performance in the communication skills OSCE, (2) to use the findings obtained from the analysis to determine whether the rating instrument needed to be revised to improve its effectiveness, (3) to use the results from the analysis to guide the instrument revision process, and (4) to compare the original CIS Scale to the modified rating instrument to determine whether the modifications helped improve the scale's functioning, thus in effect enhancing the validity of the inferences made from scores on the communication skills OSCE. In the course of evaluating the effectiveness of these two rating instruments, we demonstrate how researchers can analyze OSCE rating data to provide validity evidence related to response processes.

## Method

### Research design

We carried out the study in two phases. The first phase was a retrospective analysis of the communication skills OSCE ratings for internal medicine residents obtained in 2003, in which SPs used the CIS scale to rate the performance of residents. We identified certain items and scales on that rating instrument that did not function effectively and revised the rating instrument to address those weaknesses. We piloted the revised instrument with a small group of SP trainers and medical faculty members and then further revised the instrument based on the comments obtained from the pilot study. This led to a development of a revised rating instrument for communication skills assessment called the Revised UIC Communication and Interpersonal Skills (RUCIS) scale.

In the second phase of the study, we implemented the RUCIS scale in the 2007 communication skills OSCE for internal medicine residents. We carried out an analysis to evaluate the effectiveness of the revised rating instrument in order to determine whether the instrument modifications helped improve the effectiveness of the instrument. Both the 2003 and 2007 communication skills OSCEs were mandatory formative assessments conducted as part of the standard curriculum of the residency program.

## Participants

Participants in the 2003 communication skills OSCE included 68 internal medicine residents (51% PGY-2 and 49% PGY-3; 66% male and 34% female) and 8 SPs (38% male and 62% female). Participants in the 2007 communication skills OSCE included 85 internal medicine residents (54% PGY-1 and 46% PGY-2; 47% male and 53% female) and 17 SPs (29% male and 71% female).

## Rating instruments

The CIS Scale, which SPs used to rate the performance of residents in the 2003 communication skills OSCE, is an 18-item rating instrument. Each item asks SPs to provide an agreement rating using a 5-category rating scale, in which 1 corresponds to “strongly disagree” and 5 corresponds to “strongly agree.” Since all items are statements of desirable communication behaviors, higher ratings indicate higher level of communication competence (See Appendix A).

The RUCIS Scale, which SPs used to rate the performance of residents in the 2007 communication skills OSCE, is a 13-item rating instrument. Each item contains a short description of the particular aspect of communication under consideration and four behaviorally anchored rating categories unique to each item. For each item, the lowest rating category always describes the least appropriate behavior for that aspect of communication, while the highest rating category always describes the most appropriate behavior for that aspect. In addition to the four rating categories for each item, six items also have a “not applicable” option that SPs could use when they did not observe the behavior related to that aspect of communication (See Appendix B).

## SP training

In the 2003 communication skills OSCE, all the SPs took part in an intensive training program to learn how to portray the cases and how to rate resident performance before participating in the OSCE. The training program included a review and discussion of the case script and repeatedly practicing the appropriate portrayal of the cases under the supervision of a trainer. Training on the CIS scale included a review and discussion of the scale and practice using it to rate a videotaped or observed performance. There was no attempt to reach agreement between the SP and trainer in the ratings they assigned, but divergent ratings were noted and discussed. The trainer ensured that each SP could portray the case consistently and rate the performance of residents to the trainer’s satisfaction before the SP was allowed to participate in the communication skills OSCE.

In the 2007 communication skills OSCE, all the SPs also took part in an intensive SP training program similar to the training for the 2003 communication skills OSCE to ensure an accurate portrayal of the cases before participating in the OSCE. However, this time we employed a frame-of-reference (FOR) approach in training the SPs to provide ratings (Bernadin and Buckley 1981). Prior to training, a group of SP trainers reviewed selected videotaped OSCE sessions and provided a consensus “gold standard” rating for each item in each encounter. During the training sessions SPs rated the selected videotaped OSCE sessions using the RUCIS scale, compared their ratings to the trainers’ “gold standard” ratings, and discussed the rationale for the gold standard. By practicing and receiving feedback from several videotaped OSCE sessions, the SPs developed a common rating standard (i.e., frame) by which to evaluate residents’ performances.

### OSCE administrations

Both OSCEs employed the same cases and the same administration format. Six residents were assessed in each half-day session. In each session, each resident encountered six different SPs in six different clinical scenarios (cases). In each case, residents spent 10 min in the encounter with the SP, 5 min reviewing task-related educational materials while the SP rated the performance, and another 5 min receiving verbal feedback from the SP. The task-related educational materials consisted of printed documents describing effective ways to interact with a patient in the situation they just encountered. The verbal feedback session provided SPs and residents with the opportunity to discuss effective and ineffective behaviors observed during the encounter, and to practice techniques that the SP suggested. The SP did not inform the resident of his/her specific ratings. The six communication tasks that residents encountered were: (1) providing patient education, (2) obtaining informed consent, (3) dealing with a patient who refuses treatment, (4) counseling an elderly patient who has been abused, (5) giving bad news to a patient, and (6) conducting a physical examination. We repeated the OSCE sessions once or twice a week until all residents had the opportunity to participate in the OSCE, which took 2 and 4 months, for the 2003 and 2007 communication skills OSCE, respectively.

### Analyses

Because the OSCE is a multi-faceted assessment method where the rating of a resident's performance depends upon many factors, including the communication competence of the resident, the difficulty of the item on the rating instrument, the severity of the SP, and the difficulty of the case, we used a many-faceted Rasch measurement (i.e., Facets) model (Linacre 1989) to analyze the data. The Facets model uses a logarithmic function of the odds of receiving a rating in a given category as compared to the odds of receiving a rating in the next lower category to define the communication competence of residents, the difficulty of items, the severity of SPs, and the difficulty of cases. All measures of these four facets are reported on the logit scale, which is a linear, equal interval scale. Higher logit measures indicate more competent residents, more difficult items, more severe SPs, and more difficult cases. Because there were multiple rating categories for each item, the Facets model also calculated a set of *step thresholds* for each item. (A step threshold is the transition point between two adjacent categories, where the probabilities of receiving a rating in the two categories are equal.) We used the Facets computer program (Linacre 2005) to conduct the analyses.

To ensure that the analyses to obtain validity evidence based on response processes would be based on reliable data, we first examined the degree of reproducibility of residents' communication competence measures—validity evidence related to the internal structure of test scores. We calculated a measure of internal consistency reliability, the resident separation reliability, which is an index analogous to KR-20 or Cronbach's Alpha. Because ratings of multiple items on the same case by the same SP can be dependent on one another, which could lead to overestimation of reliability (Sireci et al. 1991; Thissen et al. 1989), we used cases (rather than items) as scoring units. That is, we averaged the ratings a SP gave to all items in a given case to produce a case score, which we considered as one rating in the Facets analysis.

An effective rating instrument for an OSCE should produce ratings that satisfy two tests related to response processes. The first one involves determining whether each rating scale functioned appropriately (i.e., were the categories on the scales that the SPs used

well-defined, mutually exclusive, and exhaustive). The second one involves determining whether each item on the rating instrument functioned properly (i.e., when evaluating each resident's performance, did SPs assign ratings for each item in a consistent fashion).

We used the following six criteria (Linacre 2004) as guidelines for determining whether each rating scale category for each item functioned effectively (i.e., to determine whether the rating categories of each item were well-defined, mutually exclusive, and exhaustive):

- (1) There should be at least 10 ratings in each rating category to allow accurate calibration of step thresholds.
- (2) The frequency distribution of ratings across categories should have a uniform or unimodal pattern. If SPs use only a few of the rating categories and rarely use other rating categories, the resulting irregular distribution of ratings indicates a poorly functioning scale that cannot effectively differentiate residents according to their levels of communication competence.
- (3) The average measures of residents' communication competence should increase as the rating categories increase. In other words, residents who receive ratings in higher categories should have higher overall communication competence measures than those who receive ratings in lower categories.
- (4) The step thresholds should increase as the rating categories increase. This criterion mirrors the third criterion. Failure of step thresholds to increase as the rating categories increase is called *step disordering*, which suggests that SPs may have difficulty differentiating the performance of residents in those categories. One or more of the rating categories for a particular item may not be clearly defined.
- (5) The step thresholds should advance at least 1 logit, but not more than 5 logits. The finding that two step thresholds advance by less than 1 logit would suggest that those two rating categories are practically inseparable. That is, SPs may not be able to reliably differentiate between them. On the other hand, step thresholds that are too far apart are an indication of a possible dead zone on the scale where measurement loses its precision.
- (6) The outfit mean-square value for each rating category should be less than 2.0. An outfit mean-square value is a statistical index that indicates how well the ratings in each category fit the measurement model. Its value can range from 0 to infinity, with an expected value of 1. A high outfit mean-square value for a rating category is an indicator that some SPs used that rating category in an unexpected or surprising manner that was inconsistent with the way that other SPs used that category.

In addition to evaluating the functioning of the scale categories, we evaluated fit statistics for each item on the instrument to determine whether SPs provided aberrant ratings on any items, which might indicate problematic response processes. These fit statistics are indices that indicate how well the rating data for each item fit the measurement model. In this study, we examined both outfit and infit mean-square statistics for each item. We calculated an outfit mean-square value for each item by dividing the sum of the squared standardized residuals for the item by its degree of freedom. (A residual is the difference between the rating a SP assigned a resident on an item and the rating the measurement model predicted the SP would assign.) This calculation produces a value that can range from 0 to infinity, with an expectation of 1.0. Values larger than 1.0 indicate the presence of unmodeled noise in the ratings for that item (i.e., unexpected ratings that SPs assigned when evaluating residents, given how SPs assigned ratings for other items). By contrast, values less than 1.0 indicate that there was too little variation in the ratings SPs assigned for that item (Linacre and Wright 1994; Wright and Masters 1982). However, outfit

mean-square values are very sensitive to outlier ratings. To reduce the influence of outlier ratings, we weighted each squared standardized residual by its information function before we summed them. (This involved applying differential weights to standardized residuals. That is, residuals that resulted from SP ratings of items and cases that were far too easy or too difficult for residents received less weight than those that resulted from SP ratings of items and cases that were at the appropriate difficulty level for residents.) This calculation produced an infit mean-square statistic that has the same distribution and interpretation as an outfit mean-square statistic, but is more immune to the influence of the ratings for residents on items or cases that are far too easy or difficult for them. Wright and Linacre (1994) recommended that an appropriate mean-square fit statistic for judge-mediated ratings should be in the range of 0.4–1.2.

From the analysis of the 2003 communication skills OSCE ratings, we identified the items and rating categories on the CIS Scale that did not function effectively according to one or more of these criteria. We then used these findings to guide the development of a modified rating instrument—the RUCIS Scale. We implemented the RUCIS Scale in the 2007 communication skills OSCE and evaluated the effectiveness of the revised instrument using the same criteria to determine whether the modifications helped improve the effectiveness of the instrument, thus in effect enhancing the validity of the score interpretation.

## Results

### Evaluating the effectiveness of the CIS scale

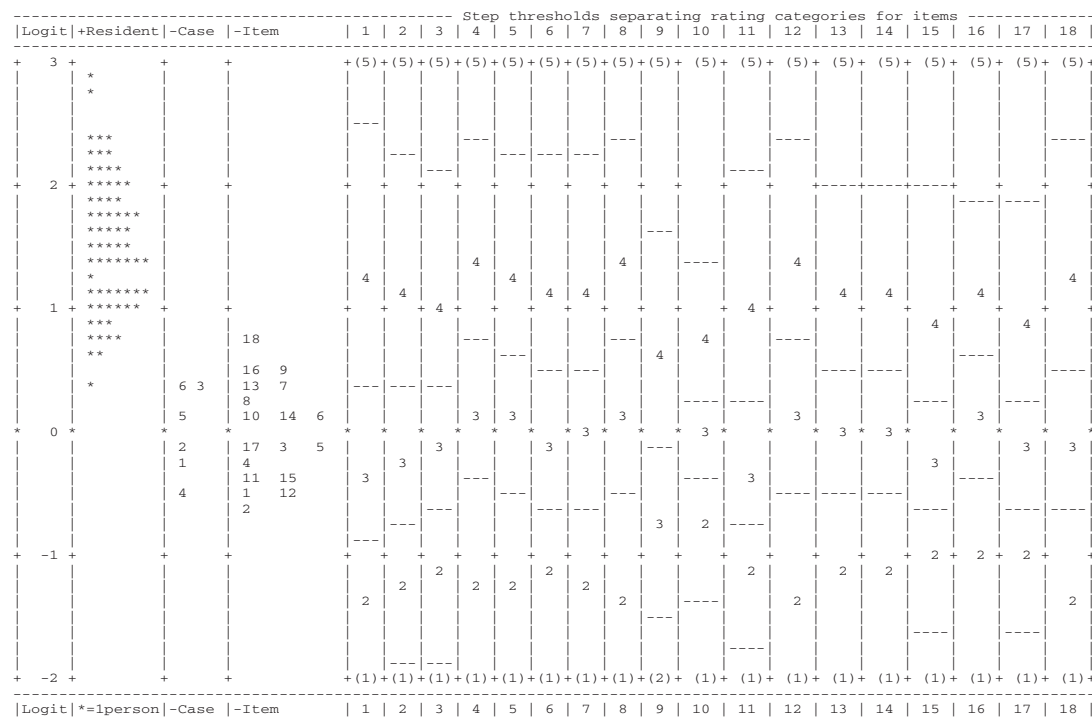
The analysis of the 2003 communication skills OSCE revealed that this group of residents was highly competent relative to the items and cases on the CIS Scale (Table 1). The average resident communication competence measure was higher than the average item and case difficulty measures, and there were few items or cases appropriate for measuring the communication competence of residents who were in the upper range of the communication competency continuum (i.e., in the 0.75–2.5 logits range). These findings suggest that these items and cases were not very well suited to measuring the communication competence of this group of residents (i.e., it was a relatively easy assessment for them). Using cases as scoring units, our analysis yielded a resident separation reliability of 0.74.

**Table 1** Summary of measures obtained from the analysis of the communication skills OSCEs

Measurement facets	Minimum (logits)	Maximum (logits)	Mean (logits)	SD (logits)
A. 2003 Communication skills OSCE				
Resident competence	−0.40	2.44	0.78	0.61
Item difficulty	−0.71	0.83	0	0.44
Case difficulty	−0.45	0.30	0	0.25
B. 2007 Communication skills OSCE				
Resident competence	−1.85	1.68	−0.17	0.68
Item difficulty	−0.91	0.98	0	0.60
Case difficulty	−0.99	0.65	0	0.49

The problematic alignment between the resident communication competence measures and the item and case difficulty measures is clearly demonstrated in Fig. 1, a simplified construct map we obtained from the analysis, showing the relationships between three of the four facets in our analysis. The first column displays the equal interval logit measures. The second column shows the resident communication measures. More competent residents appear higher in the column, while less competent residents appear lower in the column. The third and fourth columns show the cases and items ordered by difficulty. Difficult items and cases appear higher in the columns (e.g., items 18, 16, and 9, and cases 3 and 6), while easy items and cases appear lower in the columns (e.g., items 1, 12, and 2, and case 4). Columns 5–22 show how SPs used the 5-category rating scale for each item on the CIS Scale. A horizontal line across a column indicates the point at which the probability of a resident receiving the next higher rating begins to exceed the probability of receiving the lower rating (i.e., a step threshold). According to this construct map, the most likely rating that SPs assigned on all the CIS items was a 4 or 5. Another interesting finding is SPs did not use the scale in an identical fashion when assigning ratings on these 18 items, as demonstrated by having different ranges of communication competence measures for each rating category across items (e.g., the region of rating category 3 is not the same across all items).

The analysis of the 2003 communication skills OSCE revealed that the CIS Scale did not meet several of Linacre’s (2004) guidelines for evaluating rating scale category effectiveness. We summarized these results in Table 2. First, only five items had more than 10 ratings in all five categories. The 5-category agreement rating scale actually functioned as a 4-category rating scale. SPs rarely assigned ratings of 1. The items on the CIS Scale



**Fig. 1** A construct map showing the misalignment between the resident communication competence measures and the item and case difficulty measures for the 18 items on the CIS Scale

**Table 2** Comparing the functioning of the CIS scale (2003) and RUCIS scale (2007) using Linacre's (2004) guidelines

	CIS scale 5-category scales 18 items	RUCIS scale 4-category scales 13 items
Resident separation reliability	0.74	0.71
Criteria for evaluating the functioning of the categories on each rating scale		
At least 10 ratings in each category	5 items (28%)	6 items (46%)
Uniform/unimodal distribution of ratings across categories	1 item (6%)	12 items (92%)
Residents with higher category ratings have higher overall communication competence measures	7 items (39%)	12 items (92%)
No step disordering	9 items (50%)	11 items (85%)
Step thresholds advance by at least 1 logit, but not more than 5 logits	1 item (6%)	10 items (77%)
An outfit mean-square value <2.0 for each rating category	11 items (61%)	13 items (100%)
Criteria for evaluating the functioning of the items on the instrument		
Outfit mean-square values <1.2	14 items (78%)	12 items (92%)
Infit mean-square values <1.2	16 items (89%)	13 items (100%)

appeared to be relatively easy for these residents, resulting in an unbalanced distribution of ratings across the five rating categories: about 70–80% of all ratings were 4 s or 5 s. The only item that exhibited an acceptable rating distribution was item 18, which showed a unimodal distribution that peaked in the middle categories.

The analysis also revealed that some SPs experienced difficulty in differentiating between the middle categories of the 5-category agreement scale, as demonstrated by the failure of the average measures and step thresholds to increase properly along with the rating categories. Only seven items (items 4, 5, 6, 9, 11, 16, and 18) exhibited proper advancement of average resident communication competence measures as the rating categories increased. Nine items (items 2, 4, 6, 10, 11, 13, 14, 15, and 17) showed disordered step thresholds. Seven items (items 7, 8, 9, 10, 13, 14, and 15) had one or more rating categories with outfit mean-square values equal to or greater than 2, reflecting inconsistent use of the categories. Only one item (item 12) had all adjacent step thresholds separated by at least one logit. The other 17 items had one or more step thresholds that were too close to adjacent thresholds, especially for step thresholds in the middle of the scale. However, none of the 18 items had step thresholds that advanced by more than five logits, suggesting that there were no significant gaps between the categories.

We summarized item fit statistics in Table 3. Four items (items 3, 5, 10, and 15) had outfit mean-square values higher than 1.2, indicating that some SPs assigned ratings for those items that were unexpectedly high or low, given the other ratings that the SPs assigned. Items 10 and 15 had infit mean-square values higher than 1.2. A close examination of the unexpected ratings for items 10 (I felt you encouraged me to ask questions) and 15 (I felt you were careful to use plain language) revealed that six out of eight SPs were inconsistent in rating item 10, and seven out of eight SPs were inconsistent in rating item 15. Apparently, the SPs did not have a shared understanding of what they were evaluating when using these two items. This finding suggested that we needed to revise these items to make them clearer to SPs.



**Table 3** Summary of item fit statistics

Item fit statistics	Minimum	Maximum	Mean	SD
A. 2003 Communication skills OSCE				
Outfit mean-square values	0.71	2.35	1.08	0.37
Infit mean-square values	0.76	1.72	1.00	0.23
B. 2007 Communication skills OSCE				
Outfit mean-square values	0.86	1.22	1.00	0.08
Infit mean-square values	0.86	1.16	1.00	0.07

### Modifying the rating instrument

The findings from our validity study revealed that there were several aspects of the CIS Scale that did not function well. Using these findings as our guide, we worked with medical faculty and SPs to revise the CIS Scale in several ways. Instead of using a single Likert-style agreement rating scale that was applicable to all items on the instrument, we devised a behaviorally anchored rating scale (BARS) (Bernardin and Smith 1981; Smith and Kendall 1963) that provided a detailed description of the specific communication behavior characteristic of each rating category for each item. Our expectation was that the change in the scale format would make each rating scale more specific to the context of a particular item and less open to SPs' idiosyncratic interpretations.

Because our analysis revealed that the lowest rating category on the CIS Scale was a non-functioning category, we decided to change the scale format from 5-category scales to 4-category scales. To address the problem of an unbalanced rating distribution in which 70–80% of ratings were positive ratings, while only 20–30% of ratings were neutral or negative ratings, we developed 4-category scales that were saturated on the positive side. In other words, we created a separate rating scale for each item with only one category describing inadequate performance and three categories describing satisfactory communication behaviors that exemplified progressively higher levels of performance.

We also provided a "not applicable" option for six items. Our goal was to eliminate some unexpected ratings that SPs assigned in the neutral category of the agreement scale when they found themselves unable to rate a certain aspect of communication during the encounter because they did not observe any evidence that the resident engaged in that aspect.

Although we did not change the content coverage of the rating instrument, we revised the items to eliminate redundancy and improve their clarity. We combined into one item the redundant items that addressed the same aspect of communication. Specifically, we combined items 1 and 2 into an item on friendly communication; combined items 7, 8, and 9 into an item on discussion of options; combined items 10, 11, and 12 into an item on encouraging questions; and combined items 13 and 14 into an item on providing a clear explanation. We created a new item on physical examination to allow SPs to separate the act of providing an explanation of a physical examination from the act of providing an explanation about medical conditions.

Finally, we attempted to make several items more difficult by requiring that residents demonstrate communication behaviors that are more sophisticated and/or difficult to perform to qualify for a rating in the highest category.

These modifications led to the development of a revised rating instrument, called the RUCIS Scale (Appendix B), which we later used in the scoring of residents' performance in the 2007 communication skills OSCE.

Evaluating the effectiveness of the RUCIS scale

The analysis of the 2007 communication skills OSCE revealed that this set of items was better targeted for measuring the communication competence of the residents (See Table 1 and columns 2–4 of Fig. 2). The distribution of resident communication competence measures was better aligned with the distributions of item and case difficulty measures than was the case for the 2003 communication skills OSCE. Using cases as scoring units, our analysis yielded a resident separation reliability of 0.71. Despite fewer numbers of items on the RUCIS Scale, the ratings on this revised instrument could achieve the same level of internal consistency reliability as the level obtained from the CIS Scale.

Table 2 provides a point-by-point comparison of the findings from our analyses of the functioning of the CIS Scale and the RUCIS Scale. We found that seven items on the revised instrument still had fewer than 10 ratings assigned in the lowest category. Beyond this, nearly all the items and rating scales appearing on the RUCIS Scale satisfied Linacre’s criteria. All items but one had a uniform distribution of ratings that peaked in the middle or at the high end. Item 5 (interest in me as a person) was the only item that had a rating distribution that peaked in rating category 1. Item 2 (respectful treatment) was the only item that did not show increasing average measures as rating categories increased. The rating categories for all items fit the measurement model (i.e., all outfit mean-square values for the rating categories were less than 2). Items 7 and 12 were the only two items with disordered step thresholds. Some of the distances between step thresholds for Items 5, 6, and 10 were too narrow (i.e., less than one logit apart). However, all the step thresholds for

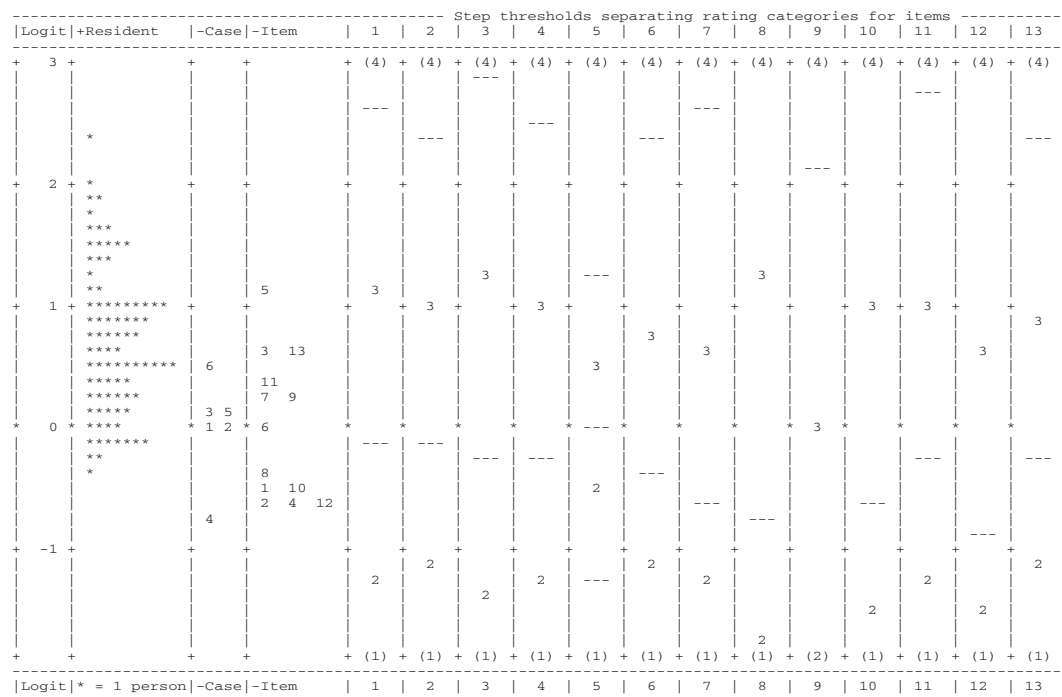


Fig. 2 A construct map showing the better alignment between the resident communication competence measures and the item and case difficulty measures for the 13 items on the RUCIS Scale



the other items were appropriately ordered and advanced by more than one logit but less than five logits.

We summarized item fit statistics obtained from the analysis of the 2007 communication skills OSCE in Table 3. All items showed good fit to the measurement model according to their infit mean-square values. Item 5 (interest in me as a person) was the only item with an outfit mean-square value higher than 1.2, indicating too much unexplained variance in the ratings that SPs assigned for this item. Thus, it was the only item that needed close examination to try to determine what made it difficult for SPs to use the item's behaviorally anchored rating scale to assign consistent ratings.

## Discussion

This study demonstrated the process of using validity evidence obtained from a Facets analysis to help revise an assessment instrument such as an OSCE rating scale. Validation is a continuing process of gathering and evaluating various sources of evidence to determine whether that evidence supports (or refutes) the proposed score interpretation. The two phases of this study correspond to the two stages of validation that Kane (2006) described. In the first phase of the study, we focused on finding ways to build a measurement instrument that possessed appropriate psychometric properties that would support the intended uses of OSCE scores. This phase corresponds to the *development stage* of validation. In the second phase, we critically evaluated whether the newly developed rating instrument actually functioned as predicted. This phase corresponds to the *appraisal stage* of validation.

In the first phase of our study, validity evidence based on response processes helped us identify several aspects of the CIS Scale that did not function as intended. The validity evidence suggested that the 5-category Likert-style agreement scale functioned as an unbalanced 4-category rating scale (i.e., most of the ratings were positive ratings, while only a few ratings were neutral or negative). This finding indicated that the items on the CIS Scale were too easy for this sample of residents. Results from our analyses also suggested that some SPs were unable to differentiate performance in the middle categories of the scale. Additionally, we found that some SPs assigned a number of surprising or unexpected ratings for item 10 (I felt you encouraged me to ask questions) and for item 15 (I felt you were careful to use plain language), suggesting that these SPs were not able to consistently apply the rating criteria for these two items to rate some residents' performances. All these pieces of validity evidence provided useful information to guide the development of a revised rating instrument in our attempt to address these weaknesses of the CIS Scale.

In the second phase of our validity study, we implemented the revised instrument in a later administration of the communication skills OSCE and carried out the same types of analyses that had revealed the inadequacies of the CIS Scale. We considered this as a test of whether the revised instrument could withstand the same validity challenges as its predecessor. We found that in many aspects the RUCIS Scale helped improve score interpretability. The SPs more consistently applied the rating criteria to rate residents' performances. The items on the RUCIS Scale fit the measurement model quite well. Providing a clear description of communication behavior that was appropriate for each rating category for the two misfitting items on the CIS Scale (items 10 and 15) helped eliminate confusion among SPs in rating these two aspects of communication (as demonstrated by good item fit statistics for items 7 and 10 on the RUCIS Scale).

However, the modifications we made to the rating instrument did not address all the validity issues we identified in the CIS Scale. There was one area in which the revised instrument did not show significant improvement over its predecessor. When using the behaviorally anchored rating scales, SPs still assigned only a few ratings in the lowest rating category of many items. This could be due to a restricted range of communication competence among the particular sample of residents assessed. We developed the RUCIS Scale with a broad range of communication competence in mind—from very incompetent physicians to very competent physicians. The subjects included in the 2007 communication skills OSCE were a single group of residents in one residency program. This limited the range of observable communication skills that SPs were likely to see. If we were to assess a broader range of subjects, ranging from medical students in their early years of training to experienced physicians practicing in various specialties from geographically diverse medical settings, the SPs would be more likely to observe a broader range of communication behaviors and would be more likely to employ the full range of rating categories appearing on each behaviorally anchored rating scale. Testing this hypothesis would require that researchers conduct additional studies to evaluate validity generalization (American Educational Research Association et al. 1999). That is, we are suggesting that researchers carry out studies to determine the extent to which variations in situational facets (e.g., residents from different residency programs, different SPs, etc.) may affect the assignment of ratings. The studies would help us determine how generalizable the results we obtained are across subjects that differ in education and experience, and across SPs.

Another possible explanation for non-uniform distributions of ratings is that SPs may have been uncomfortable assigning very low ratings to residents. If this were the case, then SP trainers could address this issue during the training, helping SPs understand that it is appropriate (and expected) that they will assign low ratings if they see evidence of physician behaviors that warrant those ratings. However, we would be a bit cautious in following this criterion too strictly. For a formative assessment or in a summative assessment where residents had not been properly trained, a uniform distribution of ratings is to be expected. However, in a summative assessment where the majority of residents have practiced the skills so that they are well prepared for the communication tasks, a skew distribution of ratings where only few residents would have ratings in lower categories can be obtained, which might not suggest a problem with the rating instrument.

The evaluation of item fit statistics for the RUCIS scale revealed that item 5 (interest in me as a person) was the only item with too much unexplained variance in its ratings. Interestingly, two of the SPs were responsible for 65% of the statistically significantly unexpected ratings (i.e., ratings with an absolute value of their standardized residuals larger than 2.0) for this item. This finding suggests that the source of error in the ratings of item 5 might be due to the inconsistency of only two SPs, and that the fit of the item might be improved through additional training of these two SPs to clear up any confusion they might have experienced when rating this item.

Although we carried out the study in two phases that addressed both the development and appraisal stages of validation (Kane 2006), this study by no means presents a complete validation effort. Validation is an ongoing process of gathering various sources of evidence to support proposed score interpretations. One could consider the findings from the second phase of this study as input to further modify the rating instrument to craft an even more psychometrically sound assessment, thus cycling back to the development stage of validation once again. For example, our results suggest that item 5 on the RUCIS Scale is still problematic, since it continues to show inadequate fit to the measurement model. Additional modification on this item is a potential area for further instrument improvement.

There are some limitations related to the interpretation and application of the findings from this study. The first limitation is the instrument's limited focus on patient-centered medical communication skills. The ACGME's (1999) definition of communication skills emphasizes the importance of the ability to communicate not only with patients but also with other members of a healthcare team. The RUCIS Scale does not address the skills needed to communicate effectively with other members of a healthcare team. The psychometric properties of the RUCIS Scale demonstrated in this study might only apply to its use in an OSCE setting where SPs are trained properly on how to use the rating instrument. Another limitation of this study is the homogeneity of the resident samples we examined. Since our participants were internal medicine residents from a single training program, they were relatively homogeneous in their medical communication experience. Communication behaviors that were not observed in these residents might be evident when other groups of physicians are assessed. A multi-center trial of the rating instrument that involves medical schools from various geographical regions could study how the RUCIS Scale functions with a more heterogeneous group of physicians.

We hope that the findings from our study will benefit the medical education community in several ways. First, the product of this validation effort—the RUCIS Scale, along with validity evidence that supports its uses in the communication skills OSCE, should serve the needs of many residency programs, especially given the increasing interest in communication skills assessment that the ACGME Outcome Project has generated. Second, our study provides a concrete example of how to use a many-faceted Rasch measurement approach to improve the quality of SP rating instruments and to provide validity evidence based on response processes as outlined in the 1999 *Standards for Educational and Psychological Testing* (American Educational Research Association et al. 1999). Finally, this study generated many interesting ideas for future research.

## Appendix A

### Items on the Patient-Centered Communication and Interpersonal Skills (CIS) scale

1. I felt you greeted me warmly upon entering the room.
2. I felt you were friendly throughout the encounter. You were never crabby or rude to me.
3. I felt that you treated me like we were on the same level. You never “talked down” to me or treated me like a child.
4. I felt you let me tell my story and were careful to not interrupt me while I was speaking.
5. I felt you were telling me everything; being truthful, up front and frank; not keeping things from me.
6. I felt you showed interest in me as a “person.” You never acted bored or ignored what I had to say.
7. I felt that you discussed options with me.
8. I felt you made sure that I understood those options.
9. I felt you asked my opinion, allowing me to make my own decision.
10. I felt you encouraged me to ask questions.
11. I felt you displayed patience when I asked questions.
12. I felt you answered my questions, never avoiding them.

13. I felt you clearly explained what I needed to know about my problem; how and why it occurred.
14. I felt you clearly explained what I should expect next.
15. I felt you were careful to use plain language and not medical jargon when speaking to me.
16. I felt you approached sensitive/difficult subject matters, such as religion, sexual history, tobacco/drug/alcohol history, sexual orientation, giving bad news, etc., with sensitivity and without being judgmental.
17. I felt the resident displayed a positive attitude during the verbal feedback session.
18. If given the choice in the future, I would choose this resident as my personal physician.

Note: All items are rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree).

## Appendix B

### Revised UIC Communication and Interpersonal Skills scale

#### *Instruction*

Please choose the option that best describes how you feel toward the resident's communication skills. Some items also have a "not applicable" option. Select this option when the context of the case does not allow you to observe that aspect of the resident's performance.

#### (1) **Friendly communication**

- You did not greet me, or greeted me perfunctorily, or communicated with me rudely during the encounter.
- Your greeting and/or behavior during the encounter was generally polite but impersonal or distant.
- You greeted me warmly and communicated with me in a friendly, personal manner throughout the encounter.
- Your greeting and overall communication were friendly and compassionate. Your tone of voice was appropriate for the situation. Overall, you created an exceptionally warm and friendly environment that made me feel comfortable to tell you all of my problems.

#### (2) **Respectful treatment**

- You showed an obvious sign of disrespect during the encounter. You treated me as an inferior.
- You did not show disrespect to me. However, I observed some signs of condescending behavior. Although I believe it was unintentional, it made me feel that I was not at the same level with you.
- You gave several indications of respecting me. If there was a physical exam, this includes draping me appropriately.
- You were exceptionally respectful throughout the encounter. Your verbal and non-verbal communication showed respect for my privacy, my opinions, my rights, and my socioeconomic status.

**(3) Listening to my story**

- You rarely gave me any opportunity to tell my story or frequently interrupted me while I was talking, not allowing me to finish what I said. Sometimes I felt you were not paying attention (for example, you asked for information that I already provided).
- You let me tell my story without interruption, or only interrupted appropriately and respectfully. You seemed to pay attention to my story and responded to what I said appropriately.
- You allowed me to tell my story without interruption, responded appropriately to what I said, and asked thoughtful questions to encourage me to tell more of my story.
- You were an exceptional listener. You encouraged me to tell my story and checked your understanding by restating important points.

**(4) Honest communication**

- You did not seem truthful and frank. I felt that there might be something that you were trying to hide from me.
- You did not seem to hide any critical information from me.
- You explained the facts of the situation without trivializing negative information or possibilities (e.g., side effects, complications, failure rates).
- You were exceptionally frank and honest. You fully explained the positive and negative aspects of my condition. You openly acknowledged your own lack of knowledge or uncertainty, and things you would have to consult with others. When appropriate, you also suggested I seek a second opinion.
- Not applicable. There was no information for the resident to provide.

**(5) Interest in me as a person**

- You never showed interest in me as a person. You only focused on the disease or medical issue.
- In addition to talking about my medical issue, you spent some time getting to know me as a person.
- You spent some time exploring how my medical issue affects my personal or social life.
- You were exceptionally interested in me as a person. You not only explored how my medical problem affects my personal and social life, but also showed your willingness to help me address those challenges.

**(6) Discussion of options/plans**

- You did not explain any options or plans; you just told me what you would do without asking for my opinion.
- You explained options to me, but did not involve me in decision making. If you solicited my opinion, you just ignored it. You made all the decisions for me based on your medical opinion.
- You discussed options with me, made recommendations, solicited my opinion regarding the options/plans, and incorporated my opinion into your medical planning.

- You not only solicited my input, but also explored the reasons for my choice and showed your understanding and respect for my decisions by negotiating a mutually agreeable plan.
  - Not applicable. There were no decisions to be made in this case.
- (7) **Encouraging my questions**
- You did not solicit questions, or frequently avoided my questions, or did not provide helpful answers.
  - You sometimes asked if I had questions, but seldom waited at least 5 seconds to allow me to formulate questions. You addressed my questions briefly without avoiding them.
  - You actively encouraged me to ask questions, paused to allow me to formulate them, and provided clear and sufficient answers to all of my questions.
  - You actively encouraged me to ask questions several times during the encounter, with sufficient wait time. You spent significant time and effort to answer my questions clearly and confirmed that I understood the answer and that my concerns were addressed.
- (8) **Providing clear explanation**
- You rarely explained things to me; you did not help me better understand my situation.
  - You gave me only brief explanations of my situation; you did not help me understand what would happen next.
  - You gave me a full and understandable explanation of my situation, pertinent findings, and important next steps.
  - You gave me a full explanation of my situation, your thinking about it and your recommendation, and probed my understanding by letting me summarize pertinent information.
  - Not applicable. There was nothing to be explained in this case.
- (9) **Physical examination**
- You never or rarely warned me about what you were going to do with my body. You also never or rarely explained what you found from the physical examination.
  - You did not warn me about what you were going to do with my body, OR did not explain to me pertinent findings (both negative and positive) from your physical examination.
  - You told me what you were going to do to my body AND described what you found.
  - You helped me understand clearly what you were going to do to my body. You also provided clear explanation of what you found from the physical examination and the implications of your findings for my situation.
  - Not applicable. There was no physical examination in this case.
- (10) **Appropriate vocabulary**
- You used vocabulary that was too simple or too complex for me, or frequently used medical terms without explaining them to me. Sometimes I could not understand what you told me without asking for explanations of terms you used.



- Your vocabulary was generally appropriate but you sometimes inadvertently used medical terms without explaining them to me.
  - Your vocabulary was appropriate and if needed you provided brief explanations of any medical terms you used without need for prompting.
  - Your vocabulary was appropriate and you always provide clear and full explanation of relevant medical terms you used. In addition, you helped me better my understanding of my condition with the medical terms you explained to me.
- (11) **Sensitive subject matters (e.g., sexual history, tobacco/alcohol/drug use, religious/cultural issues, giving bad news, or difficult emotional states)**
- You never warned me before approaching sensitive subject matters. You seemed judgmental and clearly expressed your disapproval of my positions or feelings, making me feel uncomfortable about discussing these subjects or feelings with you.
  - You were careful and non-judgmental in discussing sensitive subject matters. However, you did not express understanding of my feelings and did not provide much emotional support.
  - You were sensitive about discussing difficult subjects and were respectful of my feelings. I never sensed that you were judgmental or disapproving of my positions or feelings on these subjects. You showed empathic understanding of my position or feelings and provided appropriate emotional support.
  - You were unusually empathic, sensitive and respectful of me and of my feelings and provided exceptional emotional support. In addition, you verbally reflected these back to me (e.g., “You sound sad”) to show your understanding.
  - Not applicable. There were no sensitive subject matters in this case.
- (12) **Receptiveness to feedback**
- You did not seem open to my feedback about your performance. You responded defensively or dismissively too many of my comments.
  - You listened to my feedback agreeably but passively. You did not actively participate during the feedback session.
  - You were able to describe some of your own effective and ineffective behaviors, were attentive to my comments, and had an open discussion with me about alternative behaviors.
  - You actively solicited additional feedback and showed signs of integrating my feedback into your behavioral repertoire. For example, you tried to role-play the communication techniques I suggested.
  - Not applicable. I provided no feedback.
- (13) **Do I want to see you again as my personal physician?**
- I did not feel comfortable in communicating with you at all. I would rather see a different physician.
  - I think you were okay in general and might come see you again.
  - I was impressed by the way you communicated with me. I would like to see you again.

- I was very impressed with you. I think you are one of the best physicians I have ever seen. I would feel very comfortable discussing any medical problems with you, and would recommend you to my friends.

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## ► Question & Comments

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