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Clinical decisions presented to patients in hospital encounters: a cross-sectional study using a novel taxonomy

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Title: Clinical decisions presented to patients in hospital encounters: a cross–sectional study using a novel taxonomy

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Abstract

Objective: To identify, classify and quantify all clinical decisions that emerged in a sample of patient-physician encounters in a hospital setting.

Design: Cross-sectional descriptive evaluation of hospital encounters videotaped in 2007-2008 using a novel taxonomy to identify and classify clinically relevant decisions.

Participants and setting: 372 patients and 58 physicians from 17 clinical specialties in ward round (WR), emergency room (ER) and outpatient (OP) encounters in a Norwegian University Hospital.

Results: The 372 encounters contained 4976 clinically relevant decisions. The average number of decisions per encounter was 13.4 (min-max 2-40, SD 6.8). The overall distribution of the ten topical categories in all encounters was: defining problem 30%, evaluating test result 17%, drug-related 13%, gathering additional information 10%, contact-related 10%, advice and precaution 8%, therapeutic procedure-related 5%, deferment 4%, legal and insurance-related 2%, treatment goal 1%. Across three temporal categories the distribution of decisions was 71% here-and-now, 16% preformed, and 13% conditional. On average, there were 15.7 decisions per encounter in internal medicine specialties, 7.1 in ear-nose-throat-encounters, and 11.0-13.6 in the remaining specialties. WR encounters contained significantly more drug-related decisions than OP encounters (p=0.031) and preformed decisions than ER and OP encounters (p<0.001). ER encounters contained significantly more gathering additional information decisions than OP and WR encounters (p<0.001) and less problem defining decisions than WR encounters (p=0.028). There was no significant difference in average number of decisions related to physician's and patient's age or gender.

Conclusions: Patient-physician encounters contain a larger amount of clinical decisions than described in previous studies. Comprehensive descriptions of how decisions are

communicated in encounters opens up for analyzing practices with respect to efficiency and quality, on provider or system level.

Strengths and limitations of this study:

- The study comprises a large material of video-recorded patient-physician encounters including 17 different clinical specialties and three practice settings (outpatients, inpatients on the ward, emergency room).
- Statistical analyses of decisions within various categories were performed by estimating linear mixed models accounting for random and fixed effects.
- The encounters were recorded at a single hospital over a limited time-period, and the taxonomy has not been tested in general practice or psychiatry.

Introduction

Decision-making is a key activity – perhaps the key activity – in health care. (1) Alvan Feinstein's 1967 harbinger "Clinical Judgment" (2) spawned a body of research and theory that has advanced the field of decision making in health care. (1,3-7) Feinstein later concluded (8) that the field's emphasis on quantitative models derived from nonclinical sources has left central challenges on how decisions are made at the bedside or in the clinic, open for pursuit.

In the context of patient-physician encounters, decision-making processes result in diagnoses, choice of treatment, selection of tests, provision of relevant information and scheduling of follow-up. Traditionally these decisions have been made by the physician, but in recent decades these decisions - that govern how resources and time are invested in the care of patients - are all under increasing pressure to live up to normative standards like evidence-based medicine (EBM), patient-centered care, patient safety culture and provider professionalism.

In both research and clinical practice, the focus has often been on single decisions related to a specific context. In EBM the aim is to formulate an answerable question, search the literature, critically appraise the information and build the decision-making process around best available evidence. (9) Patient safety programs select key triggers identifiable as the cause of adverse events, with the aim of flagging them for prescriptive measures. (10,11) In the context of patient-centered care, decisions are increasingly framed within a shared decision-making (SDM) paradigm. Research and implementation of SDM target single decisions related to a specified, predetermined topic, focusing on difficult decisions with two or more options, where medical evidence provides no clear guidance. (12-14)

Only a handful of studies have attempted to describe the frequency and types of decisions that are made in medical encounters. (15-19) These studies all aimed to assess level of patient involvement in decision-making and the selection of decisions appears limited by

this aim. In two of the studies, Braddock et al. defined a medical decision as "a verbal statement committing to a particular course of action". (15) This definition is broad and includes actions leading to diagnostic tests, prescriptions, referrals and instructions regarding diet and physical activity. However, it does not capture decisions that govern the subsequent "courses of action," such as evaluations of findings and tests, and interpretations concerning diagnosis, prognosis and etiology, likely because in the context of patient involvement such decisions are not considered relevant.

Decision scientists (20,21) describe "problem solving" and "decision-making" as two separate cognitive processes, and in theory this is a sensible distinction, but in clinical practice the boundaries between the two are constantly blurred. Our starting point was that normative and prescriptive approaches to clinical decision-making need a descriptive framework for identification and classification of clinical decisions that is precise, detailed and exhaustive. In a previous study, we developed a taxonomy for identifying and classifying all clinically relevant decisions. (22,23) Building on the work by Braddock et al, we defined a clinically relevant decision as "a verbal statement committing to a particular course of clinically relevant action and/or statement concerning the patient's health that carries meaning and weight because it is said by a medical expert". (23) We applied this definition and the taxonomy to 372 videotaped hospital encounters in order to identify, classify and quantify all clinical decisions that emerged in hospital-based patient-physician encounters.

Methods

Conceptual framework

The process of establishing a sensitive definition of a decision in a clinical context, the identification of decisions, and the development of a novel taxonomy have been described in detail elsewhere. (22,23) The analytic process was informed by the three prototypical

strategies for qualitative research, as described by Crabtree and Miller. (24) Our choice of a broad definition of clinical decisions was based on three criteria; (1) all decisions have to require some element of medical judgment, (2) they have to relate to the actual patient's concrete situation and are therefore distinct from general medical information, and (3) because of (2) they represent important conclusions relevant for the patient to understand and remember, even if not presented as decisions as such. We chose these criteria with the clear aim to describe the medical decisional landscape as it is presented to patients in face-to-face interactions.

We built a taxonomy with two dimensions; a topical dimension with ten categories and a temporal dimension with three categories (see Table 1). The taxonomy was named DICTUM; the Decision Identification and Classification Taxonomy for Use in Medicine (full and updated version of the codebook is available at www.ocher.no/resources/dictum).

Participants

Available for our study by broad consent were 380 video-recorded patient-physician encounters collected during 2007-2008 as a part of a randomized controlled trial to evaluate the effect of a 20-hour communication skills course. (25) The physicians were randomly drawn from all physicians under 60 years of age working in non-psychiatric clinical departments, 71 of 103 (69%) invited physicians consented to participate in the trial, and 59 provided broad consent. Patients were recruited consecutively on the days the participating physicians were available, and 94% agreed to have their encounter videotaped. (26) At the time of the encounter, the patients and physicians gave broad consent to further studies of communication and were unaware of our subsequent focus on identification and classification of decisions. Both the study where the tapes were collected and our study of clinical decisions were approved by the Regional Ethics Committee for Medical Research of South-East Norway, in 2007 and 2009 respectively.

Videotape coding

Before the start of coding, we evaluated how consistent we were able to use the taxonomy as a team. Using a maximum variation approach (27), we selected sets of five videos from different clinical settings and specialties, with variation in gender and age in both patients and physicians. The four researcher/physicians coded independently, and this process was repeated three times, resulting in minor adjustments to taxonomy categories the first two times and reaching satisfying consistency on a final version the third time. We tested reliability using Krippendorff's alpha-agreement for content coding with multiple coders (28), and coded a final set of five new videos resulting in a Krippendorff's alpha of 0.79. Cut-off value for Krippendorff's alpha needed for coded variables to be reliable has been set at 0.80. (28) Using the categories of the taxonomy, we created a coding scheme in the observation software "Observer XT" (Noldus Information Technology, Wageningen, the Netherlands). All 372 videos were coded by EHO. Every 20th video was coded independently by PG to check for drift. Two-coder inter-rater reliability and intra-rater reliability for EHO in five videos sampled with maximum variation were both good, with Cohen's kappa of 0.61 and 0.77 respectively. (29)

Statistical analysis

Once coding was completed we calculated simple descriptive statistics (30) using "IBM SPSS Statistics 34" (IBM Corporation, Armonk, NY, USA). In the analysis, participants were stratified according to gender, relevant age groups (children/adult patients/old patients and experienced/inexperienced physicians), specialty of physician, and type of encounter. The data exhibit hierarchical structure with decisions nested within the doctor and the doctor nested within the specialty. The number of decisions within various categories was thus compared by estimating linear mixed models with random effects for doctors nested within specialty or for doctors only. Akaike's Information Criteria (AIC) (31) was applied to choose

the best model with respect to random effects. The distribution of number of decisions across three temporal categories in three different settings was compared by estimating a linear mixed model with fixed effects for temporal category, setting and interaction between the two. The model assessing the number of decisions within each topical category contained fixed effects for settings. The differences in the average number of decisions between various categories of characteristics of patients and doctors were assessed by first estimating a bivariate linear mixed model for number of decisions with fixed effect for relevant characteristic. Next, a multiple model was estimated. As judged by AIC, a model with random intercepts for doctors only fitted data best, hence specialty was included into the model as a fixed effect instead. All linear mixed models were estimated by SAS MIXED procedure using "SAS 9.4" (SAS Institute Inc., Cary, NC, USA).

Results

We reviewed 380 videotapes, eight were excluded from the final analysis: one encounter was incompletely captured (showing only six of 53 minutes), and one physician whose seven encounters all exceeded 60 minutes was excluded, as this practitioner represented an extreme outlier. We further analyzed 372 videotapes, which contained 4976 decisions. The average number of decisions per encounter was 13.4, min-max 2-40, standard deviation (SD) 6.8, 95% confidence interval (CI) 12.7-14.1.

Characteristics of participants and encounters

The characteristics of physicians and patients are shown in table 2. The average duration of the 372 encounters was 22 minutes (min-max 3-66). In 87 (27%) of 372 of the encounters communication was observed as challenging either because the patient was a child or an immigrant with limited Norwegian fluency. In three encounters the patient was a child with immigrant parents with limited Norwegian fluency.

Categories 1-19 and 21 of the International Statistical Classification of Diseases and Related Health Problems Revision 10 (ICD-10) (32) were present in the material, with diseases of the circulatory system (13%) and neoplasms (10%) being most frequent. See Table 3 for full distribution of primary diagnoses.

81 (22%) of 372 encounters contained a clinical procedure comprised by the Norwegian classification of surgical and medical procedures, the most frequent being obstetrical or gynecological ultrasound (27%), echocardiography (21%), stress-echocardiogram (9%), pacemaker-test (7%), neurography/electromyography (7%), anoscopy/rectoscopy (7%) and urethrocystoscopy (6%).

Characteristics of clinical decisions

Table 4 shows the distribution of decisions across the taxonomy's ten topical categories. The two categories "defining problem" and "evaluating test result" together accounted for 47% of decisions, and were also the two categories present in the largest proportion of encounters (95% and 78% respectively). Decisions categorized as "drug-related", "contact-related", "gathering additional information" or "advice and precaution" were frequently present in a majority of the encounters. The less frequent categories, "therapeutic procedure-related" "deferment", "legal and insurance-related" and "treatment goal" together accounted for 12% of the decisions, but were present in 38%, 35%, 18% and 15% of encounters respectively.

Table 5 presents the distribution of decisions across clinical settings and temporal categories - decisions which had already been made and were brought into the encounter by the physician (preformed decisions), decisions made in the present (here-and-now decisions), and decisions prescribing future actions given a certain course of events (conditional decisions). Decisions made here-and-now were the most frequent in all settings, but as many as 39.3% of the decisions conveyed on ward rounds (WR) had been made before the

encounter started. The proportion of preformed decisions was significantly higher in these encounters than in the other two settings (p <0.001).

Table 6 shows the distribution of topical categories by clinical setting and temporal categories. ER encounters contained a significantly larger proportion of decisions in the category "gathering additional information" than OP and WR encounters (p <0.001) and a significantly smaller proportion of "defining problem" statements than WR encounters (p=0.028). WR encounters comprised a significantly larger proportion of "drug-related" decisions than OP encounters (p=0.031). OP encounters contained a significantly larger proportion of advice and precaution statements than ER encounters (p=0.035). There were no significant differences in proportions between the three settings in the other topical categories. With regard to temporality, the topical categories "evaluating test result", "defining problem" and "drug-related" accounted for 78% of the preformed decisions, while "drug-related", "contact related", "advice and precaution" and "therapeutic procedure-related"-statements made up 77% of the conditional decisions.

The largest topical category, "defining problem" comprised diagnostic conclusions (39%), prognostic statements (27%), etiological inferences (19%) and evaluations of state of health (15%). "Evaluating test result"-statements were predominantly positive (73%), i.e. the physician interpreted the test result as satisfactory. "Gathering additional information" was largely made up by decisions to order tests (87%). "Drug-related" and "therapeutic procedure-related" decisions most frequently concerned start of therapy (40% and 55%, respectively). "Drug-related" decisions also frequently described altering or maintaining therapy (17% and 25%), while a larger proportion of "therapeutic procedure-related" decisions concluded to refrain from action (30% versus 10% in the drug-related category). 92% of the encounters contained a decision about whether to schedule a follow-up appointment or not. 26% of advice statements were given as a precaution, the remaining as advice relevant to the patient's

health and situation. 64% of deferment decisions transferred the responsibility for making the decision to another person, most frequently the patient's general practitioner.

Table 7 shows the average number of decisions per encounter distributed across gender, age, setting and specialty with corresponding 95% CI. According to the multiple linear mixed model, there were no significant differences for gender, age or setting. Female physicians communicated 14.7 decisions per encounter, while male physicians communicated 12.7 (p=0.053). Compared to internists who had on average 15.7 decisions per encounter, earnose-throat (ENT)-physicians and obstetrics and gynecology (OB/GYN)-physicians communicated significantly fewer decisions; 7.1 (p=0.006) and 11.0 (p=0.023) respectively. Compared to ENT-physicians, neurologists and pediatric physicians communicated significantly more decisions; 13.6 (p=0.029) and 13.4 (p=0.041) respectively. Besides internists and ENT-physicians, the remaining six groups of hospital specialists had on average between 11.1 and 13.6 decisions. Of the 628 "drug-related" decisions, 299 were found in the 121 internal medicine encounters, meaning an average of 2.5 "drug-related" decisions per encounter, compared to an average of 1.3 in the other specialties combined.

Figure 1 illustrates the average number of decisions communicated by each physician in their encounters (min-max 2-8 encounters per physician). The three physicians who averaged the highest (29.5, 23.5, 23.3 respectively) were women. The remaining physicians averaged between 6.7 and 20.5 decisions. The range of decisions per encounter varied substantially from physician to physician, the smallest range was 5 (9-14) and the largest was 29 (11-40).

Discussion

We set out to identify and classify all clinically relevant decisions communicated in 372 hospital encounters using the novel taxonomy DICTUM. (22) We found that patients were

exposed to more than 13 medically relevant decisions per patient-physician encounter. The encounters in this study were representative of everyday activity in non-psychiatric clinical departments in a large Norwegian hospital. Sorted across topical categories, decisions were diverse; mostly diagnostic, but almost half were of other kinds. Sorted across temporal categories, the majority of decisions were made in the present, but a substantial amount was brought into the encounter as new information, or presented as conditional depending on future trajectories. With the exception of internal medicine and ENT encounters, we found only minor differences among disciplines. Also, decision frequencies were not associated with patient or physician characteristics. The question is if this resemblance between specialties and physicians, could indicate that DICTUM captures a general structure of how decisions are communicated in medical encounters.

Observed differences, e.g. a higher frequency of preformed decisions in ward rounds, a lower total frequency in ENT encounters, more "gathering information"-decisions in ER encounters and more "drug-related" decisions in internal medicine encounters, are all findings that could be expected from these different clinical contexts. WR encounters are commonly preceded by chart review, huddles or formal meetings where providers either alone or as a team make judgments and decisions without the patient present. ENT encounters commonly deal with only one concern. In ER encounters the diagnostic process is at its earliest and gathering additional information through tests or consulting with a colleague or a next of kin is what drives the process forward. Internists deal with more drug-related decisions, partly because their patients often have several previous medications in need of review and partly because diseases cared for by internists frequently have the potential for improvement or prevention through pharmaceutical therapy.

The difference between male and female physicians represent two decisions per encounter, however was not statistically significant and we are not convinced that the

difference is of clinical significance either. On the individual level, however, the averages and ranges of decisions varied greatly also within disciplines. Illustrated by averages and ranges, respectively, Figure 1 shows large inter-physician and intra-physician variability; the first possibly reflecting each physician's communication style and the latter possibly associated with the patient's communication style and the relevant clinical context.

Overall, these observations of similarities and differences support that we have provided a valid description of the amount and pattern of medically relevant decisions in everyday hospital practice.

One may challenge our definition of decisions. Previous studies of decisions in patient-physician encounters have reported substantially lower frequencies, varying between on average three and seven decisions per encounter in five different studies. (15-19) All these studies have identified decisions with the aim of describing patient involvement in decisions. Neither of these studies included diagnostic decisions (comprised by our first three categories), and if diagnostic decisions are subtracted from our material, our findings align with the findings from previous studies. The inherent elements of medical encounters that we have defined as diagnostic decisions, have in previous studies been framed as clinical questions that physicians attempt to answer. Ely et al. developed a taxonomy of clinical questions to assess how physicians deal with the challenges of treatment, choice of tests and also diagnosis, prognosis and etiology, by building their framework around clinical questions instead of the decisions that produce the answers. (33,34) DICTUM may help studies on how physicians and patients deal with and answer these clinical questions in dialogue.

A detailed and exhaustive description of clinical decisions as they appear to patients in medical encounters could aid clinical studies and assessments of real-life practice with normative or prescriptive aims. DICTUM offers the possibility of assessing all points in time where decisions are communicated. The basis of diagnoses, etiology, prognoses, care plans,

follow-up, use of time and resources can all be scrutinized with a normative approach, on provider or system level. Additional relevant data would be necessary to distinguish between desired standard and substandard medicine. Such data, e.g. patient or physician surveys or interviews, patient chart reviews or peer review of encounters, could be collected at the time of decision-making but also followed up at a later stage. For inpatient care, an observation framework exceeding the patient-physician encounter could shed light on which and how decisions are made when the patient is not present – decisions that we in this study observe are presented to patients as information ("preformed decisions").

Introducing physicians and patients to the DICTUM taxonomy before a clinical encounter, might affect how decisions are made and communicated. Discussing the observed decisions with physicians and patients after the encounter could provide insight into the lapses in comprehension, meaning and implications of the information shared during the encounter.

Providers and institutions strive to deliver high quality care, increasingly focusing on evidence, patient preferences, safety, efficiency and use of resources. Raising awareness around which decisions need to be made, how they are made and who should make them, may not have causal effect on performance, but it will put the punctuation marks of care out in the open.

There are several limitations to our study. The taxonomy has not been tested in general practice or psychiatric practice, nor in other hospitals than the one in our study. We have studied a videotaped material collected over a limited period of time. Although there may be cultural differences varying over time, between hospitals, regions, countries and how health care is financed and legislated, we argue that the taxonomy captures a universal structure of how decisions are communicated in meetings between patients and physicians. Use in other settings is needed to further evaluate the taxonomy's applicability, reliability and validity.

Conclusion

Patient-physician encounters contain a large amount of clinical decisions. Exhaustive descriptions of how decisions are communicated in encounters, opens up for analyzing practices with respect to efficiency and quality, on provider or system level.

Footnotes

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Contributors: EHO and PG contributed equally to this study. PG conceived the study and put together the study group. EHO analysed the first 30 videos and selected statements to be discussed in the study group. EHO, JCF, ES and PG took part in all seven group meetings and all four independently analysed the 20 videos for inter-rater reliability measurements. Because of language barrier RMF did not part take in analysis of the videos, but transcribed and translated statements were presented to RMF during the analytic phase. EHO analysed 372 videos. PG analysed every 20th of these videos to check for inter-rater drift. EHO and PG analysed the data with simple descriptive statistics. JSB performed multi-level statistical analyses. EHO, JCF, ES, RMF, JSB and PG analysed the data and reviewed the manuscript

for its intellectual content. All authors had full access to all the data and take responsibility for the integrity of the data and accuracy of the analysis. EHO is guarantor.

Transparency declaration: EHO affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Table 1: The Decision Identification and Classification Taxonomy for Use in Medicine (DICTUM)

	Topical category	Category description	Example of statement conveying a decision
1	Gathering additional information	Decision to obtain information from other source than patient interview, physical examination and patient chart; ordering new tests/diagnostic procedures for the patient, actively seeking external information from other party (other hospital, general practitioner, family member etc) or discussing patient with other physician or health care personnel	"I am going to order an MRI of your skeleton"
2	Evaluating test result	Simple, normative assessments of clinical findings and tests	"Your blood pressure is high. 180/100 is high"
3	Defining problem	Complex, interpretative assessments that defines what the problem is and reflects a medically informed conclusion, thereby being either a diagnostic conclusion, an evaluation of state of health, an etiological inference or a prognostic judgment	"This is basically what we call osteoarthritis"
4	Drug-related	Decision to start, refrain from, stop, alter or maintain a drug regimen	"I will give you a four day treatment of dexametasone"
5	Therapeutic procedure-related	Decision to intervene upon a medical problem, plan, perform or refrain from therapeutic procedures of a medical nature	"We cannot operate more on you"
6	Legal and insurance-related	Medical decision concerning the patient, which is based upon or restricted by a legal regulation or financial arrangements	"I will write you a sick leave note"
7	Contact-related	Decision regarding admittance or discharge from hospital, scheduling of control and referral to other part of the health care system	"She is so weak that she should be admitted"
8	Advice and precaution	Decision to give the patient advice or precaution, thereby transferring responsibility for action from provider to patient	"You should stop smoking completely"
9	Treatment goal	Decision to set defined goal for treatment and thereby being more specific than giving advice	"We want to get the AIc down between 7 and 8"
10	Deferment	Decision to actively delay decision or a rejection to decide upon problem presented by patient	"You have to discuss this with your family doctor"
	Temporal category	Category description	Example of statement conveying a decision
A	Preformed	Decisions which have already been made and are brought into the encounter by the physician as information	"We have started you on some anticoagulants"
В	Here-and-now	Decisions made in the present	"I will get an ultrasound of your leg tonight"
С	Conditional	Decisions prescribing future actions given a certain course of events	"If the pills don't alleviate your pain, you may double the dosage"

Table 2: Characteristics of the physicians and patients in our sample*

		N (%)
Patients	Men	182 (49)
	Women	190 (51)
	Total	372 (100)
	Age 0-17	81 (22)
	Age 18-60	167 (45)
	Age >60	124 (33)
	Total	372 (100)
Physicians	Men	35 (60)
	Women	23 (40)
	Total	58 (100)
	Age <40	30 (52)
	Age ≥40	28 (48)
	Total	58 (100)
	Internal medicine (cardiology, respiratory medicine,	19 (33)
	nephrology, gastroenterology, endocrinology, hematology, infectious diseases, oncology)	
	Surgery (gastro surgery, urology, thorax & vascular surgery)	7 (12)
	Orthopedics	5 (9)
	Ear-nose-throat (ENT)	2 (4)
	Anesthesiology	3 (5)
	Obstetrics & gynecology (OBGYN)	6 (10)
	Pediatrics	8 (14)
	Neurology	8 (14)
	Total	58 (100)
Setting	Outpatient (OP)	291 (78)
- · · · · 8	Ward round (WR)	58 (16)
	Emergency room (ER)	23 (6)
	Total encounters	372 (100
*The 372 na	tient-physician encounters that was included in our analysis	`

Table 3: Primary diagnoses coded in the 372 encounters according to International Statistical Classification of Diseases and Related Health Problems Revision 10 (ICD-10)

ICD-10 categories (classification letter)	N (%)
Diseases of the circulatory system (I)	50 (13)
Neoplasms (C/D)	38 (10)
Symptoms, signs, findings not classified elsewhere (R)	35 (9)
Diseases of the digestive system (K)	32 (9)
Diseases of the muscoloskeletal system (M)	29 (8)
Diseases of the genitourinary system (N)	28 (8)
Endocrine disorders (E)	27 (7)
Diseases of the nervous system (G)	25 (7)
Diseases of the respiratory system (J)	25 (7)
Pregnancy, childbirth (O)	18 (5)
Injury due to external cause (S/T)	16 (4)
Infectious disease (A/B)	14 (4)
Congenital malformations (Q)	8 (2)
Factors influencing health status and contact with health	6(1)
system (Z)	
Diseases of the ear (H)	5 (1)
Diseases of the skin (L)	4(1)
Diseases of the blood (D)	3 (1)
Mental and behavioral disorders (F)	3 (1)
Conditions originating in perinatal period (P)	3 (1)
Preoperative visit without known problem	3 (1)
Total	372 (100)

Table 4: Distribution of decisions across ten topical categories, number of encounters with different decision categories present, and averages per encounter.

	Category	N (%)	Present in number of	Average per	Min- max
			encounters (%)	encounter	
1	Gathering additional information	504 (10.1)	227 (61.0)	1.4	0-8
2	Evaluating test result	829 (16.7)	289 (77.7)	2.2	0-13
3	Defining problem	1512 (30.4)	355 (95.4)	4.1	0-18
4	Drug-related	628 (12.6)	223 (59.9)	1.7	0-10
5	Therapeutic procedure-related	260 (5.2)	142 (38.2)	0.7	0-7
6	Legal and insurance-related	90 (1.8)	68 (18.3)	0.2	0-4
7	Contact-related	496 (10.0)	288 (77.4)	1.3	0-5
8	Advice and precaution	397 (8.0)	205 (55.1)	1.1	0-8
9	Treatment goal	70 (1.4)	56 (15.1)	0.2	0-3
10	Deferment	190 (3.8)	129 (34.7)	0.5	0-5
	Total	4976 (100)	372 (100)	13.4	2-40

Table 5: Distribution of decisions across three temporal categories in three different settings

	Total	Outpatient	Ward round	Emergency room
Decisions	4976 (100)	3905	812	259
Temporal category		Numbe	er of decisions (%	<u>/o)</u>
Preformed	797 (16.0)	456 (11.7)	319 (39.3) 1	22 (8.5)
Here-and-now	3534 (71.0)	2921 (74.8)	401 (49.4) 2	212 (81.8)
Conditional	645 (13.0)	528 (13.5)	92 (11.3)	25 (9.7)

¹ Significantly higher than in outpatient (p<0.001) and emergency room (p<0.001)

Table 6. Distribution of topical decision categories on settings and temporal categories

	Outpati ent	Ward round	Emerge ncy room	Preformed	Here-and- now	Conditi onal
Topical category			Number	of decisions (%)	
Gathering additional information	368 (9.4)	66 (8.1)	$70 (27.0)^1$	85 (10.7)	365 (10.3)	54 (8.4)
Evaluating test result	683 (17.5)	100 (12.3)	46 (17.8)	236 (29.6)	591 (16.7)	2 (0.3)
Defining problem	1201 (30.8)	253 (31.2)	58 (22.4) ²	265 (33.2)	1183 (33.5)	64 (9.9)
Drug-related	438 (11.2)	154 $(19.0)^3$	36 (13.9)	117 (14.7)	344 (9.7)	167 (25.9)
Therapeutic procedure-related	216 (5.5)	40 (4.9)	4 (1.5)	24 (3.0)	148 (4.2)	88 (13.6)
Legal and insurance-related	67 (1.7)	22 (2.7)	1 (0.4)	7 (0.9)	63 (1.8)	20 (3.1)
Contact- related	388 (9.9)	86 (10.6)	22 (8.5)	51 (6.4)	310 (8.8)	135 (20.9)
Advice and precaution	324 (8.3) ⁴	60 (7.4)	13 (5.0)	7 (0.9)	285 (8.1)	105 (16.3)
Treatment goal	60 (1.5)	7 (0.9)	3 (1.2)	3 (0.4)	67 (1.9)	-
Deferment	160 (4.4)	24 (3.0)	6 (2.3)	2 (0.3)	178 (5.0)	10 (1.6)
Total	3905 (100)	812 (100)	259 (100)	797 (100)	3534 (100)	645 (100)

Significantly higher than in outpatient (p<0.001) and ward round encounters (p<0.001)

² Significantly lower than in outpatient (p<0.001) and emergency room (p=0.003)

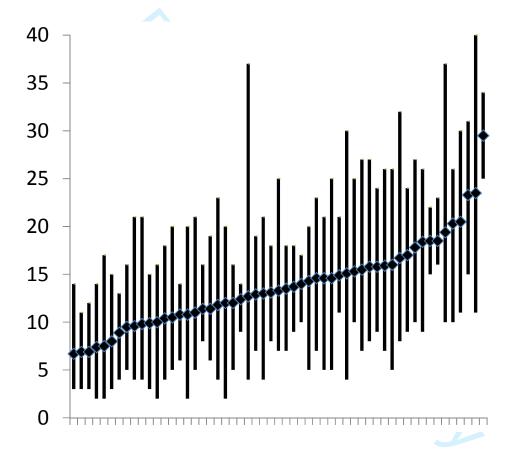
² Significantly lower than in emergency room encounters (p=0.028)
³ Significantly higher than in outpatient encounters (p=0.031)

⁴ Significantly higher than in emergency room encounters (p=0.035)

Table 7. Average of decisions per encounter across gender, age, setting and specialty

	Average (95% CI)
Physicians	
Men	12.7 (11.9-13.5)
Women	14.7 (13.4-16.0)
Age <40	13.5 (12.5-14.6)
Age ≥40	13.2 (12.3-14.2)
Patients	
Men	13.2 (12.2-14.2)
Women	13.6 (12.6-14.5)
Age 0-17	12.4 (10.8-14.0)
Age 18-60	14.1 (13.1-15.2)
Age >60	13.0 (11.9-14.2)
Setting	
Outpatient clinic	13.4 (12.6-14.2)
Ward round	14.0 (11.9-16.1)
Emergency room	11.3 (9.1-13.4)
Specialty	
Internal medicine	15.7 (14.5-16.9)
Surgery	12.1 (10.4-13.8)
Orthopedics	12.6 (10.5-14.6)
Ear-nose-throat (ENT) ¹	7.1 (4.7-9.6)
Anesthesiology	11.1 (5.1-17.1)
Obstetrics and gynecology ²	11.0 (9.3-12.7)
Pediatrics ³	13.4 (11.2-15.5)
Neurology ⁴	13.6 (11.6-15.5)
Significantly lower than inter	
² Significantly lower than inter	
³ Significantly higher than EN	
⁴ Significantly higher than EN	Γ (P=0.029)

Figure 1: Distribution of frequency of decisions in encounters for each physician. Diamonds indicate average of decisions per physician (inter-physician variability). The vertical lines indicate the range for each physician (intra-physician variability). One physician for whom we did only have broad consent for one video is not shown.



STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

For: "Clinical decisions presented to patients in hospital encounters: a cross–sectional study using a novel taxonomy"

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1, 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-8
Bias	9	Describe any efforts to address potential sources of bias	Not done
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	7-8
		(c) Explain how missing data were addressed	No missing data
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	7-8

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	Not relevant
Outcome data	15*	Report numbers of outcome events or summary measures	8-11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-11
		(b) Report category boundaries when continuous variables were categorized	8-11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12-14
Other information		7)/.	
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Clinical decisions presented to patients in hospital encounters: a cross-sectional study using a novel taxonomy

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Title: Clinical decisions presented to patients in hospital encounters: a cross–sectional study using a novel taxonomy

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Abstract

Objective: To identify and classify all clinical decisions that emerged in a sample of patient-physician encounters, and compare different categories of decisions across clinical settings and personal characteristics.

Design: Cross-sectional descriptive evaluation of hospital encounters videotaped in 2007-2008 using a novel taxonomy to identify and classify clinically relevant decisions (both actions and judgments).

Participants and setting: 372 patients and 58 physicians from 17 clinical specialties in ward round (WR), emergency room (ER) and outpatient (OP) encounters in a Norwegian University Hospital.

Results: The 372 encounters contained 4976 clinically relevant decisions. The average number of decisions per encounter was 13.4 (min-max 2-40, SD 6.8). The overall distribution of the ten topical categories in all encounters was: defining problem 30%, evaluating test result 17%, drug-related 13%, gathering additional information 10%, contact-related 10%, advice and precaution 8%, therapeutic procedure-related 5%, deferment 4%, legal and insurance-related 2%, treatment goal 1%. Across three temporal categories the distribution of decisions was 71% here-and-now, 16% preformed, and 13% conditional. On average, there were 15.7 decisions per encounter in internal medicine specialties, 7.1 in ear-nose-throat-encounters, and 11.0-13.6 in the remaining specialties. WR encounters contained significantly more drug-related decisions than OP encounters (p=0.031) and preformed decisions than ER and OP encounters (p<0.001). ER encounters contained significantly more gathering additional information decisions than OP and WR encounters (p<0.001) and fewer problem defining decisions than WR encounters (p=0.028). There was no significant difference in the average number of decisions related to the physician's and patient's age or gender.

Conclusions: Patient-physician encounters contain a larger number of clinically relevant decisions than described in previous studies. Comprehensive descriptions of how decisions both as actions and judgments are communicated in medical encounters, may serve as a first step in assessing clinical practice with respect to efficiency and quality, on a provider or system level.

Strengths and limitations of this study:

- The study comprises a large material of video-recorded patient-physician encounters including 17 different clinical specialties and three practice settings (outpatients, inpatients on the ward, emergency room).
- Statistical analyses of decisions within various categories were performed by estimating linear mixed models accounting for random and fixed effects, to ensure that observed differences were not attributable to significant clustering at doctor level.
- The encounters were recorded at a single hospital over a limited time-period, and the taxonomy has not been tested in general practice or psychiatry.

Introduction

Decision-making is a key activity – perhaps the key activity – in health care. (1) Alvan Feinstein's 1967 harbinger "Clinical Judgment" (2) spawned a body of research and theory that has advanced the field of decision making in health care. (1,3-7) Feinstein later concluded (8) that the field's emphasis on quantitative models derived from nonclinical sources had left central challenges on how decisions are made at the bedside or in the clinic, open for pursuit.

In the context of patient-physician encounters, decision-making processes result in diagnoses, choice of treatment, selection of tests, provision of relevant information and scheduling of follow-up – or the decision to do nothing. Traditionally these decisions have been made by the physician. In recent decades, these decisions - that govern how resources and time are invested in the care of patients - are all under increasing pressure to live up to normative standards like evidence-based medicine (EBM), patient-centered care, patient safety culture and provider professionalism.

In both research and clinical practice, the focus has often been on single decisions related to a specific context. In EBM, the aim is to formulate an answerable question, search the literature, critically appraise the information and build the decision-making process around best available evidence together with patient values and preferences. (9) Patient safety programs select key triggers identifiable as the cause of adverse events, with the aim of flagging them for prescriptive measures. (10,11) In the context of patient-centered care, decisions are increasingly framed within a shared decision-making (SDM) paradigm.

Research and implementation of SDM often target single decisions related to a specified, predetermined topic, focusing on difficult decisions with two or more options that patients may weigh differently. (12-14)

Only a handful of studies have attempted to describe the frequency and types of decisions that are made in medical encounters. (15-19) These studies all aimed to assess the level of patient involvement in decision-making. In two of the studies, Braddock et al. defined a medical decision as "a verbal statement committing to a particular course of action". (15) This definition is broad, including actions leading to diagnostic tests, prescriptions, referrals and instructions regarding diet and physical activity. However, it does not capture decisions that govern the subsequent "courses of action," such as evaluations of findings and tests, and interpretations concerning diagnosis, prognosis and etiology.

Decision scientists (20,21) describe "problem solving" and "decision-making" as two separate cognitive processes, and in theory this is a sensible distinction. However, medical "problem-solving" often involves "decision-making", best illustrated by the fact that diagnostic conclusions seldom reveal themselves, they have to be produced by someone. (22) Often, the path to diagnostic judgments and therapeutic actions present options that require decision-making and, due to both medical and contextual complexity, leave room for interpretation. (23)

Our starting point was that normative and prescriptive approaches to clinical decision-making need a descriptive framework for identification and classification of clinical decisions that is precise, detailed and exhaustive. In other words, before one can assess the quality of a clinical decision, one must need to know what the decision is and what it is based upon. In a previous study, we developed a taxonomy for identifying and classifying all clinically relevant decisions, both actions and judgments. (24,25) Building on the work by Braddock et al, we defined a clinically relevant decision as "a verbal statement committing to a particular course of clinically relevant action and/or statement concerning the patient's health that carries meaning and weight because it is said by a medical expert". (25) We applied this definition and the taxonomy to 372 videotaped hospital encounters in order to identify and classify all

clinical decisions that emerged in hospital-based patient-physician encounters, and to compare different categories of decisions across clinical settings and personal characteristics.

Methods

Conceptual framework

The process of establishing a sensitive definition of a decision in a clinical context, the identification of decisions, and the development of a novel taxonomy has been described in detail elsewhere. (24,25) The analytic process was informed by the three prototypical strategies for qualitative research, as described by Crabtree and Miller. (26) The two fundamental questions describing the core process of the first of the three methods coincide with our initial research questions (in brackets);

- What are the content and constituent elements (of clinically relevant decisions)?
- When does it (a clinically relevant decision) begin?

Our choice to broaden a definition of clinical decisions was based on three criteria; all decisions (1) must require some element of medical judgment, (2) must relate to the actual patient's concrete situation (i.e. are therefore distinct from general medical information), and therefore (3) represent important conclusions relevant for the patient to understand and remember, even if not presented as decisions as such. We chose these criteria with the clear aim to describe the medical decisional landscape as it is presented to patients in face-to-face interactions with physicians.

We built a taxonomy with two dimensions; a topical dimension with ten categories and a temporal dimension with three categories (see Table 1). The taxonomy was named DICTUM; the Decision Identification and Classification Taxonomy for Use in Medicine (a full and updated version of the codebook is available at www.ocher.no/resources/dictum).

Participants

Available for our study by broad consent were 380 video-recorded patient-physician encounters collected during 2007-2008 as a part of a randomized controlled trial (RCT) to evaluate the effect of a 20-hour communication skills course. (27) The original RCT comprised 497 encounters and for 380 of these both patient and physician provided written consent for the video to be available for other communication studies until 2020. In the remaining 127 encounters either the patient, the physician or both limited the written consent to the RCT only. The physicians were randomly drawn from all physicians under 60 years of age working in non-psychiatric clinical departments. Patients were recruited consecutively on the days the participating physicians were available. While the patients and physicians gave broad consent to further studies of communication, they were unaware of our subsequent focus on identification and classification of decisions. Both the original RCT and our study of clinical decisions were approved by the Regional Ethics Committee for Medical Research of South-East Norway, in 2007 and 2009 respectively.

Videotape coding

Analysis of the encounters was done through direct observation of the videotapes. Before formal coding began, we evaluated how consistently we were able to use the taxonomy as a team. Using a maximum variation approach (28), we selected sets of five videos from different clinical settings and specialties, with variation in gender and age in both patients and physicians. The four researcher/physicians coded independently, and this process was repeated three times, resulting in minor adjustments to taxonomy categories the first two times and reaching satisfactory consistency on a final version the third time. We tested reliability using Krippendorff's alpha-agreement for content coding with multiple coders (29), and coded a final set of five new videos resulting in a Krippendorff's alpha of 0.79. For coded variables to be reliable, cut-off value for Krippendorff's alpha needed has been set at 0.80. (29) Using the categories of the taxonomy, we created a coding scheme in the observation

software "Observer XT" (Noldus Information Technology, Wageningen, the Netherlands). All 372 videos were coded by EHO. Every 20th video was coded independently by PG to check for drift. Two-coder inter-rater reliability and intra-rater reliability for EHO - coding five videos one year after the initial coding - sampled with maximum variation were both good, with Cohen's kappa of 0.61 and 0.77 respectively. (30)

Statistical analysis

Once coding was completed, we calculated simple descriptive statistics (31) using "IBM SPSS Statistics 34" (IBM Corporation, Armonk, NY, USA). In the analysis, patients and physicians were stratified according to gender, relevant age groups, specialty of physician, and type of encounter. The data exhibit hierarchical structure with decisions nested within the doctor and the doctor nested within the specialty. The number of decisions within various categories was thus compared by estimating linear mixed models with random effects for doctors nested within specialty or for doctors only. Akaike's Information Criteria (AIC) (32) was applied to choose the best model with respect to random effects. The distribution of number of decisions across three temporal categories in three different settings was compared by estimating a linear mixed model with fixed effects for temporal category, setting and interaction between the two. The model assessing the number of decisions within each topical category contained fixed effects for settings. The differences in the average number of decisions between various categories of characteristics of patients and doctors were assessed by first estimating a bivariate linear mixed model for number of decisions with fixed effect for relevant characteristic. Next, a multiple model was estimated. As judged by AIC, a model with random intercepts for doctors only fitted data best, hence specialty was included into the model as a fixed effect instead. All linear mixed models were estimated by SAS MIXED procedure using "SAS 9.4" (SAS Institute Inc., Cary, NC, USA).

Results

Of 103 invited physicians, 71 (69%) consented to participate in the original trial, and 59 (57%) provided broad consent. Of 553 patients approached, 519 (94%) agreed to have their encounter videotaped for the original study and 445 (80%) provided broad consent. (33) In 65 of the encounters where patients had provided broad consent, the physicians had not: leaving a total corpus of 380 videotaped encounters available for analysis. Of these, eight were excluded from the final analysis: one encounter was incompletely captured (showing only six of 53 minutes), and one physician whose seven encounters all exceeded 90 minutes was excluded, as this practitioner represented an extreme outlier. We further analyzed 372 videotapes, which contained 4976 decisions. The average number of decisions per encounter was 13.4, min-max 2-40, standard deviation (SD) 6.8.

Characteristics of participants and encounters

The characteristics of physicians and patients are shown in Table 2. The average duration of the 372 encounters was 22 minutes (min-max 3-66). In 87 (27%) of 372 of the encounters, communication was observed as challenging either because the patient was a child or an immigrant with limited Norwegian fluency. In three encounters, the patient was a child with immigrant parents with limited Norwegian fluency.

The Table in the Appendix shows that categories 1-19 and 21 of the International Statistical Classification of Diseases and Related Health Problems Revision 10 (ICD-10) (34) were present in the material, with diseases of the circulatory system (13%) and neoplasms (10%) being most frequent. Of the 372 encounters, 81 (22%) contained a clinical procedure comprised by the Norwegian classification of surgical and medical procedures, the most frequent being obstetrical or gynecological ultrasound (27%) and echocardiography (21%) Characteristics of clinical decisions

Table 3 shows the distribution of decisions across the taxonomy's ten topical categories. The two categories identifying clinical judgements, namely "defining problem" and "evaluating test result" together accounted for 47% of decisions, and were also the two categories present in the largest proportion of encounters (95% and 78% respectively). Decisions categorized as "drug-related", "contact-related", "gathering additional information" or "advice and precaution" were frequently present in a majority of the encounters. The less frequent categories, "therapeutic procedure-related" "deferment", "legal and insurance-related" and "treatment goal" together accounted for 12% of the decisions, but were present in 38%, 35%, 18% and 15% of encounters respectively.

Table 4 presents the distribution of topical and temporal categories by clinical setting. Decisions made here-and-now were the most frequent in all settings, but as many as 39.3% of the decisions conveyed on ward rounds (WR) had been made before the encounter started. The proportion of preformed decisions was significantly higher in these encounters than in the other two settings (p <0.001). ER encounters contained a significantly larger proportion of decisions in the category "gathering additional information" compared to OP and WR encounters (p <0.001) and a significantly smaller proportion of "defining problem" statements compared to WR encounters (p=0.028). WR encounters comprised a significantly larger proportion of "drug-related" decisions than OP encounters (p=0.031). OP encounters contained a significantly larger proportion of advice and precaution statements than ER encounters (p=0.035). There were no significant differences in proportions between the three settings in the other topical categories. With regard to temporality, the topical categories "evaluating test result", "defining problem" and "drug-related" accounted for 78% of the preformed decisions, while "drug-related", "contact related", "advice and precaution" and "therapeutic procedure-related"-statements made up 77% of the conditional decisions.

Table 5 shows the average number of decisions per encounter distributed across gender, age, setting and specialty with corresponding 95% CI. According to the multiple linear mixed model, there were no significant differences for patient or physician gender, age or setting. Female physicians communicated 14.7 decisions per encounter, while male physicians communicated 12.7 (p=0.053). Compared to internists who had on average 15.7 decisions per encounter, ear-nose-throat (ENT)-physicians and obstetrics and gynecology (OB/GYN)-physicians communicated significantly fewer decisions; 7.1 (p=0.006) and 11.0 (p=0.023) respectively. Compared to ENT-physicians, neurologists and pediatric physicians communicated significantly more decisions; 13.6 (p=0.029) and 13.4 (p=0.041) respectively. Besides internists and ENT-physicians, the remaining six groups of hospital specialists had on average between 11.1 and 13.6 decisions. Of the 628 "drug-related" decisions, 299 were found in the 121 internal medicine encounters, meaning an average of 2.5 "drug-related" decisions per encounter, compared to an average of 1.3 in the other specialties combined.

Figure 1 illustrates the average number of decisions communicated by each physician in their encounters (min-max 2-8 encounters per physician). The three physicians who averaged the highest (29.5, 23.5, 23.3 respectively) were women. The remaining physicians averaged between 6.7 and 20.5 decisions. The range of decisions per encounter varied substantially from physician to physician, the smallest range was 5 (9-14) and the largest was 29 (11-40).

Discussion

We set out to identify and classify all clinically relevant decisions communicated in 372 hospital encounters using the novel taxonomy DICTUM. (22) We found that patients, on average, were exposed to more than 13 medically relevant decisions per patient-physician encounter. The encounters in this study were representative of everyday activity in non-

psychiatric clinical departments in a large Norwegian hospital. Across topical categories, decisions were diverse; although diagnostic decisions predominated, almost half were of other kinds. Across temporal categories, the majority of decisions were made in the present, but a substantial amount was brought into the encounter as new information, or presented as conditional, depending on future trajectories. With the exception of internal medicine and ENT encounters, we found only minor differences among disciplines. Also, decision frequencies were not associated with patient or physician characteristics. The question is if this resemblance between specialties and physicians, could indicate that DICTUM captures a general structure of how decisions are communicated in medical encounters?

Observed differences, e.g. a higher frequency of preformed decisions in ward rounds, a lower total frequency in ENT encounters, more "gathering information" decisions in ER encounters and more "drug-related" decisions in internal medicine encounters, are all findings that could be expected from these different clinical contexts. WR encounters are commonly preceded by chart review, huddles or formal meetings where providers, either alone or as a team, make judgments and decisions without the patient present. ENT encounters commonly deal with only one concern. In ER encounters the diagnostic process is at its earliest and gathering additional information through tests or consulting with a colleague or a next of kin is what drives the process forward. Internists deal with more drug-related decisions, partly because their patients often have several previous medications in need of review and partly because diseases cared for by internists frequently have the potential for improvement or prevention through pharmaceutical therapy.

The difference between male and female physicians represents two decisions per encounter; however, this difference was not statistically significant and we are not convinced that the difference is of clinical significance. On the individual level, however, the averages and ranges of decisions varied greatly, also within disciplines. Illustrated by averages and

ranges, respectively, Figure 1 shows large inter-physician and intra-physician variability; the first possibly reflecting each physician's communication style, and the latter possibly associated with the patient's communication style and the relevant clinical context.

One may challenge our definition of decisions. Previous studies of decisions in patient-physician encounters have reported substantially lower frequencies, varying between on average three and seven decisions per encounter in five different studies. (15-19) Each of these studies have identified decisions with the aim of describing patient involvement in decisions. These studies did not include diagnostic decisions (comprised by our first three categories); if diagnostic decisions are subtracted from our material, our findings align with the findings from previous studies. The inherent elements of medical encounters that we have defined as diagnostic decisions, have in previous studies been framed as clinical questions that physicians attempt to answer. Ely et al. developed a taxonomy of clinical questions to assess how physicians deal with the challenges of treatment, choice of tests and also diagnosis, prognosis and etiology, by building their framework around clinical questions instead of the decisions and judgments that produce the answers. (35,36) DICTUM may help studies on how physicians and patients deal with and answer these clinical questions in dialogue.

A detailed and exhaustive description of clinical decisions, as they appear to patients in medical encounters, could aid clinical studies and assessments of real-life practice with normative or prescriptive aims. DICTUM offers the possibility of assessing all points in time where decisions are communicated. The basis of diagnoses, etiology, prognoses, care plans, follow-up, use of time and resources can all be scrutinized with a normative approach, on provider or system level. Additional relevant data would be necessary to distinguish between desired standard and substandard medicine. Such data, e.g. patient or physician surveys or interviews, patient chart reviews or peer review of encounters, could be collected at the time

of decision-making but also followed up at a later stage. For inpatient care, an observation framework exceeding the duration of the patient-physician encounter could shed light on which and how decisions are made when the patient is not present – decisions that we in this study observe are presented to patients as information ("preformed decisions").

Introducing physicians and patients to the DICTUM taxonomy before a clinical encounter, might affect how decisions are made and communicated. Discussing the observed decisions with physicians and patients after the encounter, could provide insight into the lapses in comprehension, meaning and implications of the information shared during the encounter. Providers and institutions strive to deliver high quality care, increasingly focusing on evidence, patient preferences, safety, efficiency and use of resources. Raising awareness around which decisions need to be made, how they are made and who should make them, may not have causal effect on performance, but it would put the punctuation marks of care out in the open.

There are several limitations to our study. The taxonomy has not been tested in general practice or psychiatric practice, nor in other hospitals than the one in our study. From an observer perspective, we could not always determine for sure whether the decision had been made before the encounter or was made there and then. In cases where we were in doubt, we coded the decisions as being made in the present. We have studied a videotaped material collected over a limited period of time. Although there may be cultural differences varying over time, between hospitals, regions, countries and how health care is financed and legislated, we argue that the taxonomy captures a universal structure of how decisions are communicated in meetings between patients and physicians. Use in other settings is needed to further evaluate the taxonomy's applicability, reliability and validity.

Conclusion

Patient-physician encounters contain a larger number of clinical decisions than described in previous studies. Comprehensive descriptions of how decisions both as actions and judgments are communicated in encounters, may serve as a first step in assessing clinical practice with respect to efficiency and quality, on a provider or system level.

Footnotes

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Contributors: EHO and PG contributed equally to this study. PG conceived the study and put together the study group. EHO analysed the first 30 videos and selected statements to be discussed in the study group. EHO, JCF, ES and PG took part in all seven group meetings and all four independently analysed the 20 videos for inter-rater reliability measurements. Because of language barrier RMF did not part take in analysis of the videos, but transcribed and translated statements were presented to RMF during the analytic phase. EHO analysed 372 videos. PG analysed every 20th of these videos to check for inter-rater drift. EHO and PG analysed the data with simple descriptive statistics. JSB performed multi-level statistical analyses. EHO, JCF, ES, RMF, JSB and PG analysed the data and reviewed the manuscript

for its intellectual content. All authors had full access to all the data and take responsibility for the integrity of the data and accuracy of the analysis. EHO is guarantor.

Transparency declaration: EHO affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Table 1: The Decision Identification and Classification Taxonomy for Use in Medicine (DICTUM)

(DI	CTUM)		
	Topical category	Category description	Example of statement conveying a decision
1	Gathering additional information	Decision to obtain information from other source than patient interview, physical examination and patient chart; ordering new tests/diagnostic procedures for the patient, actively seeking external information from other party (other hospital, general practitioner, family member etc) or discussing patient with other physician or health care personnel	"I am going to order an MRI of your skeleton"
2	Evaluating test result	Simple, normative assessments of clinical findings and tests	"Your blood pressure is high. 180/100 is high"
3	Defining problem	Complex, interpretative assessments that defines what the problem is and reflects a medically informed conclusion, thereby being either a diagnostic conclusion, an evaluation of state of health, an etiological inference or a prognostic judgment	"This is basically what we call osteoarthritis"
4	Drug-related	Decision to start, refrain from, stop, alter or maintain a drug regimen	"I will give you a four day treatment of dexametasone"
5	Therapeutic procedure-related	Decision to intervene upon a medical problem, plan, perform or refrain from therapeutic procedures of a medical nature	"We cannot operate more on you"
6	Legal and insurance-related	Medical decision concerning the patient, which is based upon or restricted by a legal regulation or financial arrangements	"I will write you a sick leave note"
7	Contact-related	Decision regarding admittance or discharge from hospital, scheduling of control and referral to other part of the health care system	"She is so weak that she should be admitted"
8	Advice and precaution	Decision to give the patient advice or precaution, thereby transferring responsibility for action from provider to patient	"You should stop smoking completely"
9	Treatment goal	Decision to set defined goal for treatment and thereby being more specific than giving advice	"We want to get the A1c down between 7 and 8"
10	Deferment	Decision to actively delay decision or a rejection to decide upon problem presented by patient	"You have to discuss this with your family doctor"
	Temporal category	Category description	Example of statement conveying a decision
A	Preformed	Decisions which have already been made and are brought into the encounter by the physician as information	"We have started you on some anticoagulants"
В	Here-and-now	Decisions made in the present	"I will get an ultrasound of your leg tonight"
С	Conditional	Decisions prescribing future actions given a certain course of events	"If the pills don't alleviate your pain, you may double the dosage"

Table 2: Characteristics of the physicians and patients in our sample*

		N (%)
Patients	Men	182 (49)
	Women	190 (51)
	Total	372 (100)
	Age 0-17	81 (22)
	Age 18-60	167 (45)
	Age >60	124 (33)
	Total	372 (100)
Physicians	Men	35 (60)
-	Women	23 (40)
	Total	58 (100)
	Age <40	30 (52)
	Age ≥40	28 (48)
	Total	58 (100)
	Internal medicine (cardiology, respiratory medicine,	19 (33)
	nephrology, gastroenterology, endocrinology, hematology,	
	infectious diseases, oncology)	
	Surgery (gastro surgery, urology, thorax & vascular surgery)	7 (12)
	Orthopedics	5 (9)
	Ear-nose-throat (ENT)	2 (4)
	Anesthesiology	3 (5)
	Obstetrics & gynecology (OBGYN)	6 (10)
	Pediatrics	8 (14)
	Neurology	8 (14)
	Total	58 (100)
Setting	Outpatient (OP)	291 (78)
C	Ward round (WR)	58 (16)
	Emergency room (ER)	23 (6)
		` '
	Total encounters	372 (100)

Table 3: Distribution of decisions across ten topical and three temporal categories, number of encounters with different decision categories present, and averages per encounter.

	Topical category	N (%)	Present in number of encounters (%)	Average per encounter	Min- max
1	Gathering additional information	504 (10.1)	227 (61.0)	1.4	0-8
2	Evaluating test result	829 (16.7)	289 (77.7)	2.2	0-13
3	Defining problem	1512 (30.4)	355 (95.4)	4.1	0-18
4	Drug-related	628 (12.6)	223 (59.9)	1.7	0-10
5	Therapeutic procedure-related	260 (5.2)	142 (38.2)	0.7	0-7
6	Legal and insurance-related	90 (1.8)	68 (18.3)	0.2	0-4
7	Contact-related	496 (10.0)	288 (77.4)	1.3	0-5
8	Advice and precaution	397 (8.0)	205 (55.1)	1.1	0-8
9	Treatment goal	70 (1.4)	56 (15.1)	0.2	0-3
10	Deferment	190 (3.8)	129 (34.7)	0.5	0-5
	Total	4976 (100)	372 (100)	13.4	2-40
	Temporal category				
A	Preformed	797 (16.0)	213 (57.3)	2.1	0-22
В	Here-and-now	3534 (71.0)	371 (99.7)	9.5	0-31
C	Conditional	645 (13.0)	277 (74.5)	1.7	0-9
	Total	4976 (100)	372 (100)	13.4	2-40

Table 4. Distribution of topical and temporal decision categories in three different settings

		Outpatient	Ward round	Emergency room
Tota	al by topical categories N (%)	3905 (100)	812 (100)	259 (100)
1	Gathering additional information	368 (9.4)	66 (8.1)	70 (27.0) 1
2	Evaluating test result	683 (17.5)	100 (12.3)	46 (17.8)
3	Defining problem	1201 (30.8)	253 (31.2)	$58(22.4)^2$
4	Drug-related	438 (11.2)	$154 (19.0)^3$	36 (13.9)
5	Therapeutic procedure-related	216 (5.5)	40 (4.9)	4 (1.5)
6	Legal and insurance- related	67 (1.7)	22 (2.7)	1 (0.4)
7	Contact-related	388 (9.9)	86 (10.6)	22 (8.5)
8	Advice and precaution	$324 (8.3)^4$	60 (7.4)	13 (5.0)
9	Treatment goal	60 (1.5)	7 (0.9)	3 (1.2)
10	Deferment	160 (4.4)	24 (3.0)	6 (2.3)
Tota	ll by temporal categories N (%)	3905 (100)	812 (100)	259 (100)
A	Preformed	456 (11.7)	319 (39.3) 5	22 (8.5)
В	Here-and-now	2921 (74.8)	401 (49.4) ⁶	212 (81.8)
C	Conditional	528 (13.5)	92 (11.3)	25 (9.7)

¹ Significantly higher than in outpatient (p<0.001) and ward round encounters (p<0.001) ² Significantly lower than in emergency room encounters (p=0.028)

³ Significantly higher than in outpatient encounters (p=0.031)

⁴ Significantly higher than in emergency room encounters (p=0.035)

⁵ Significantly higher than in outpatient (p<0.001) and emergency room (p<0.001)

⁶ Significantly lower than in outpatient (p<0.001) and emergency room (p=0.003)

Table 5. Average of decisions per encounter across gender, age, setting and specialty

	Average (95% CI)
Physicians	<u>G</u> . ()
Men	12.7 (11.9-13.5)
Women	14.7 (13.4-16.0)
Age <40	13.5 (12.5-14.6)
Age ≥40	13.2 (12.3-14.2)
Patients	
Men	13.2 (12.2-14.2)
Women	13.6 (12.6-14.5)
Age 0-17	12.4 (10.8-14.0)
Age 18-60	14.1 (13.1-15.2)
Age >60	13.0 (11.9-14.2)
Setting	
Outpatient clinic	13.4 (12.6-14.2)
Ward round	14.0 (11.9-16.1)
Emergency room	11.3 (9.1-13.4)
Specialty	
Internal medicine	15.7 (14.5-16.9)
Surgery	12.1 (10.4-13.8)
Orthopedics	12.6 (10.5-14.6)
Ear-nose-throat (ENT) ¹	7.1 (4.7-9.6)
Anesthesiology	11.1 (5.1-17.1)
Obstetrics and gynecology ²	11.0 (9.3-12.7)
Pediatrics ³	13.4 (11.2-15.5)
Neurology ⁴	13.6 (11.6-15.5)

¹ Significantly lower than internal medicine (p=0.006)

Figure 1: Distribution of frequency of decisions in encounters for each physician. Diamonds indicate average of decisions per physician (inter-physician variability). The vertical lines indicate the range for each physician (intra-physician variability). One physician for whom we did only have broad consent for one video is not shown.

² Significantly lower than internal medicine (p=0.023)

³ Significantly higher than ENT (p=0.041)

⁴ Significantly higher than ENT (P=0.029)

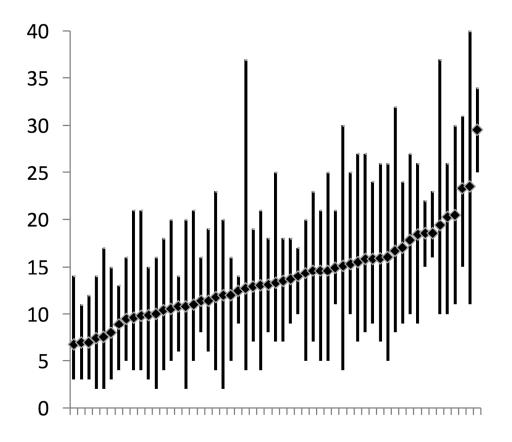


Figure 1: Distribution of frequency of decisions in encounters for each physician. Diamonds indicate average of decisions per physician (inter-physician variability). The vertical lines indicate the range for each physician (intra-physician variability). One physician for whom we did only have broad consent for one video is not shown.

286x240mm (300 x 300 DPI)



Appendix Table: Primary diagnoses coded in the 372 encounters according to International Statistical Classification of Diseases and Related Health Problems Revision 10 (ICD-10)

ICD-10 categories (classification letter)	N (%)
Diseases of the circulatory system (I)	50 (13)
Neoplasms (C/D)	38 (10)
Symptoms, signs, findings not classified elsewhere (R)	35 (9)
Diseases of the digestive system (K)	32 (9)
Diseases of the muscoloskeletal system (M)	29 (8)
Diseases of the genitourinary system (N)	28 (8)
Endocrine disorders (E)	27 (7)
Diseases of the nervous system (G)	25 (7)
Diseases of the respiratory system (J)	25 (7)
Pregnancy, childbirth (O)	18 (5)
Injury due to external cause (S/T)	16 (4)
Infectious disease (A/B)	14 (4)
Congenital malformations (Q)	8 (2)
Factors influencing health status and contact with health	6(1)
system (Z)	
Diseases of the ear (H)	5 (1)
Diseases of the skin (L)	4(1)
Diseases of the blood (D)	3 (1)
Mental and behavioral disorders (F)	3 (1)
Conditions originating in perinatal period (P)	3 (1)
Preoperative visit without known problem	3 (1)
Total	372 (100)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

For: "Clinical decisions presented to patients in hospital encounters: a cross–sectional study using a novel taxonomy"

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1, 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-8
Bias	9	Describe any efforts to address potential sources of bias	Not done
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	7-8
		(c) Explain how missing data were addressed	No missing data
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	7-8

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	Not relevant
Outcome data	15*	Report numbers of outcome events or summary measures	8-11
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-11
		(b) Report category boundaries when continuous variables were categorized	8-11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results	12-14
Other information		7)/.	
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Clinical decisions presented to patients in hospital encounters: a cross-sectional study using a novel taxonomy

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Title: Clinical decisions presented to patients in hospital encounters: a cross–sectional study using a novel taxonomy

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Abstract

Objective: To identify and classify all clinical decisions that emerged in a sample of patient-physician encounters, and compare different categories of decisions across clinical settings and personal characteristics.

Design: Cross-sectional descriptive evaluation of hospital encounters videotaped in 2007-2008 using a novel taxonomy to identify and classify clinically relevant decisions (both actions and judgments).

Participants and setting: 372 patients and 58 physicians from 17 clinical specialties in ward round (WR), emergency room (ER) and outpatient (OP) encounters in a Norwegian University Hospital.

Results: The 372 encounters contained 4976 clinically relevant decisions. The average number of decisions per encounter was 13.4 (min-max 2-40, SD 6.8). The overall distribution of the ten topical categories in all encounters was: defining problem 30%, evaluating test result 17%, drug-related 13%, gathering additional information 10%, contact-related 10%, advice and precaution 8%, therapeutic procedure-related 5%, deferment 4%, legal and insurance-related 2%, treatment goal 1%. Across three temporal categories the distribution of decisions was 71% here-and-now, 16% preformed, and 13% conditional. On average, there were 15.7 decisions per encounter in internal medicine specialties, 7.1 in ear-nose-throat-encounters, and 11.0-13.6 in the remaining specialties. WR encounters contained significantly more drug-related decisions than OP encounters (p=0.031) and preformed decisions than ER and OP encounters (p<0.001). ER encounters contained significantly more gathering additional information decisions than OP and WR encounters (p<0.001) and fewer problem defining decisions than WR encounters (p=0.028). There was no significant difference in the average number of decisions related to the physician's and patient's age or gender.

Conclusions: Patient-physician encounters contain a larger number of clinically relevant decisions than described in previous studies. Comprehensive descriptions of how decisions, both as judgments and actions, are communicated in medical encounters, may serve as a first step in assessing clinical practice with respect to efficiency and quality, on a provider or system level.

Strengths and limitations of this study:

- The study comprises a large material of video-recorded patient-physician encounters including 17 different clinical specialties and three practice settings (outpatients, inpatients on the ward, emergency room).
- Statistical analyses of decisions within various categories were performed by estimating linear mixed models accounting for random and fixed effects, to ensure that observed differences were not attributable to significant clustering at doctor level.
- The study was conducted applying a novel taxonomy, that identifies and classifies
 clinically relevant decisions in a substantially broader way than previous studies
 describing the number of decisions in medical encounters.
- The encounters were recorded at a single hospital over a limited time-period, and the taxonomy has not been tested in general practice or psychiatry.

Introduction

Decision-making is a key activity – perhaps the key activity – in health care. (1) Alvan Feinstein's 1967 harbinger "Clinical Judgment" (2) spawned a body of research and theory that has advanced the field of decision making in health care. (1,3-7) Feinstein later concluded (8) that the field's emphasis on quantitative models derived from nonclinical sources had left central challenges on how decisions are made at the bedside or in the clinic, open for pursuit.

In the context of patient-physician encounters, decision-making processes result in diagnoses, choice of treatment, selection of tests, provision of relevant information and scheduling of follow-up – or the decision to do nothing. Traditionally these decisions have been made by the physician. In recent decades, these decisions - that govern how resources and time are invested in the care of patients - are all under increasing pressure to live up to normative standards like evidence-based medicine (EBM), patient-centered care, patient safety culture and provider professionalism.

In both research and clinical practice, the focus has often been on single decisions related to a specific context. In EBM, the aim is to formulate an answerable question, search the literature, critically appraise the information and build the decision-making process around best available evidence together with patient values and preferences. (9) Patient safety programs select key triggers identifiable as the cause of adverse events, with the aim of flagging them for prescriptive measures. (10,11) In the context of patient-centered care, decisions are increasingly framed within a shared decision-making (SDM) paradigm.

Research and implementation of SDM often target single decisions related to a specified, predetermined topic, focusing on difficult decisions with two or more options that patients may weigh differently. (12-14)

Only a handful of studies have attempted to describe the frequency and types of decisions that are made in medical encounters. (15-19) These studies all aimed to assess the

level of patient involvement in decision-making. In two of the studies, Braddock et al. defined a medical decision as "a verbal statement committing to a particular course of action". (15) This definition is broad, including actions leading to diagnostic tests, prescriptions, referrals and instructions regarding diet and physical activity. However, it does not capture decisions that govern the subsequent "courses of action," such as evaluations of findings and tests, and interpretations concerning diagnosis, prognosis and etiology.

Decision scientists (20,21) describe "problem solving" and "decision-making" as two separate cognitive processes, and in theory this is a sensible distinction. However, medical "problem-solving" often involves "decision-making", best illustrated by the fact that diagnostic conclusions seldom reveal themselves, they have to be produced by someone. (22) Often, the path to diagnostic judgments and therapeutic actions present options that require decision-making and, due to both medical and contextual complexity, leave room for interpretation. (23)

Our starting point was that normative and prescriptive approaches to clinical decision-making need a descriptive framework for identification and classification of clinical decisions that is precise, detailed and exhaustive. In other words, before one can assess the quality of a clinical decision, one must know what the decision is and what it is based upon. In a previous study, we developed a taxonomy for identifying and classifying all clinically relevant decisions, both judgments and actions. (24,25) Building on the work by Braddock et al, we defined a clinically relevant decision as "a verbal statement committing to a particular course of clinically relevant action and/or statement concerning the patient's health that carries meaning and weight because it is said by a medical expert". (25) We applied this definition and the taxonomy to 372 videotaped hospital encounters in order to identify and classify all clinical decisions that emerged in hospital-based patient-physician encounters, and to compare different categories of decisions across clinical settings and personal characteristics.

Methods

Conceptual framework

The process of establishing a sensitive definition of a decision in a clinical context, the identification of decisions, and the development of a novel taxonomy has been described in detail elsewhere. (24,25) The analytic process was informed by the three prototypical strategies for qualitative research, as described by Crabtree and Miller. (26) The two fundamental questions describing the core process of the first of the three methods coincide with our initial research questions (in brackets);

- What are the content and constituent elements (of clinically relevant decisions)?
- When does it (a clinically relevant decision) begin?

Our choice to broaden a definition of clinical decisions was based on three criteria; all decisions (1) must require some element of medical judgment, (2) must relate to the actual patient's concrete situation (i.e. are therefore distinct from general medical information), and therefore, (3) represent important conclusions relevant for the patient to understand and remember, even if not presented as decisions as such. We chose these criteria with the clear aim to describe the medical decisional landscape as it is presented to patients in face-to-face interactions with physicians.

We built a taxonomy with two dimensions; a topical dimension with ten categories and a temporal dimension with three categories (see Table 1). The taxonomy was named DICTUM; the Decision Identification and Classification Taxonomy for Use in Medicine (a full and updated version of the codebook is available at www.ocher.no/resources/dictum).

Participants

Available for our study by broad consent were 380 video-recorded patient-physician encounters collected during 2007-2008 as a part of a randomized controlled trial (RCT) to evaluate the effect of a 20-hour communication skills course. (27) The original RCT

comprised 497 encounters and for 380 of these both patient and physician provided written consent for the video to be available for other communication studies until 2020. In the remaining 127 encounters either the patient, the physician or both limited the written consent to the RCT only. The physicians were randomly drawn from all physicians under 60 years of age working in non-psychiatric clinical departments. Patients were recruited consecutively on the days the participating physicians were available. While the patients and physicians gave broad consent to further studies of communication, they were unaware of our subsequent focus on identification and classification of decisions. Both the original RCT and our study of clinical decisions were approved by the Regional Ethics Committee for Medical Research of South-East Norway, in 2007 and 2009 respectively.

Videotape coding

Analysis of the encounters was done through direct observation of the videotapes. Before formal coding began, we evaluated how consistently we were able to use the taxonomy as a team. Using a maximum variation approach (28), we selected sets of five videos from different clinical settings and specialties, with variation in gender and age in both patients and physicians. The four researcher/physicians coded independently, and this process was repeated three times, resulting in minor adjustments to taxonomy categories the first two times and reaching satisfactory consistency on a final version the third time. We tested reliability using Krippendorff's alpha-agreement for content coding with multiple coders (29), and coded a final set of five new videos resulting in a Krippendorff's alpha of 0.79. For coded variables to be reliable, cut-off value for Krippendorff's alpha has been set at 0.80. (29) Using the categories of the taxonomy, we created a coding scheme in the observation software "Observer XT" (Noldus Information Technology, Wageningen, the Netherlands). All 372 videos were coded by EHO. Every 20th video was coded independently by PG to check for drift. Two-coder inter-rater reliability was good (Cohen's kappa of 0.61). Intra-rater reliability

for EHO, who coded five videos sampled with maximum variation one year after the initial coding, was good (Cohen's kappa 0.77).

Statistical analysis

Once coding was completed, we calculated simple descriptive statistics (30) using "IBM SPSS Statistics 34" (IBM Corporation, Armonk, NY, USA). In the analysis, patients and physicians were stratified according to gender, relevant age groups, specialty of physician, and type of encounter. The data exhibit hierarchical structure with decisions nested within the doctor and the doctor nested within the specialty. The number of decisions within various categories was thus compared by estimating linear mixed models with random effects for doctors nested within specialty or for doctors only. Akaike's Information Criteria (AIC) (31) was applied to choose the best model with respect to random effects. The distribution of number of decisions across three temporal categories in three different settings was compared by estimating a linear mixed model with fixed effects for temporal category, setting and interaction between the two. The model assessing the number of decisions within each topical category contained fixed effects for settings. The differences in the average number of decisions between various categories of characteristics of patients and doctors were assessed by first estimating a bivariate linear mixed model for number of decisions with fixed effect for relevant characteristic. Next, a multiple model was estimated. As judged by AIC, a model with random intercepts for doctors only fitted data best, hence specialty was included into the model as a fixed effect instead. All linear mixed models were estimated by SAS MIXED procedure using "SAS 9.4" (SAS Institute Inc., Cary, NC, USA).

Results

Of 103 invited physicians, 71 (69%) consented to participate in the original trial, and 59 (57%) provided broad consent. Of 553 patients approached, 519 (94%) agreed to have their

encounter videotaped for the original study and 445 (80%) provided broad consent. (32) In 65 of the encounters where patients had provided broad consent, the physicians had not: leaving a total corpus of 380 videotaped encounters available for analysis. Of these, eight were excluded from the final analysis: one encounter was incompletely captured (showing only six of 53 minutes), and one physician whose seven encounters all exceeded 90 minutes was excluded, as this practitioner represented an extreme outlier. We further analyzed 372 videotapes, which contained 4976 decisions. The average number of decisions per encounter was 13.4, min-max 2-40, standard deviation (SD) 6.8.

Characteristics of participants and encounters

The characteristics of physicians and patients are shown in Table 2. The average duration of the 372 encounters was 22 minutes (min-max 3-66). In 87 (27%) of 372 of the encounters, communication was observed as challenging either because the patient was a child or an immigrant with limited Norwegian fluency. In three encounters, the patient was a child with immigrant parents with limited Norwegian fluency.

The Table in the Appendix shows that categories 1-19 and 21 of the International Statistical Classification of Diseases and Related Health Problems Revision 10 (ICD-10) (33) were present in the material, with diseases of the circulatory system (13%) and neoplasms (10%) being most frequent. Of the 372 encounters, 81 (22%) contained a clinical procedure comprised by the Norwegian classification of surgical and medical procedures, the most frequent being obstetrical or gynecological ultrasound (27%) and echocardiography (21%)

Characteristics of clinical decisions

Table 3 shows the distribution of decisions across the taxonomy's ten topical categories. The two categories identifying clinical judgements, namely "defining problem" and "evaluating test result" together accounted for 47% of decisions, and were also the two categories present in the largest proportion of encounters (95% and 78% respectively). Decisions categorized as

"drug-related", "contact-related", "gathering additional information" or "advice and precaution" were frequently present in a majority of the encounters. The less frequent categories, "therapeutic procedure-related" "deferment", "legal and insurance-related" and "treatment goal" together accounted for 12% of the decisions, but were present in 38%, 35%, 18% and 15% of encounters respectively.

Table 4 presents the distribution of topical and temporal categories by clinical setting. Decisions made here-and-now were the most frequent in all settings, but as many as 39.3% of the decisions conveyed on ward rounds (WR) had been made before the encounter started. The proportion of preformed decisions was significantly higher in these encounters than in the other two settings (p <0.001). ER encounters contained a significantly larger proportion of decisions in the category "gathering additional information" compared to OP and WR encounters (p <0.001) and a significantly smaller proportion of "defining problem" statements compared to WR encounters (p=0.028). WR encounters comprised a significantly larger proportion of "drug-related" decisions than OP encounters (p=0.031). OP encounters contained a significantly larger proportion of advice and precaution statements than ER encounters (p=0.035). There were no significant differences in proportions between the three settings in the other topical categories. With regard to temporality, the topical categories "evaluating test result", "defining problem" and "drug-related" accounted for 78% of the preformed decisions, while "drug-related", "contact related", "advice and precaution" and "therapeutic procedure-related"-statements made up 77% of the conditional decisions.

Table 5 shows the average number of decisions per encounter distributed across gender, age, setting and specialty with corresponding 95% CI. According to the multiple linear mixed model, there were no significant differences for patient or physician gender, age or setting. Female physicians communicated 14.7 decisions per encounter, while male physicians communicated 12.7 (p=0.053). Compared to internists who had on average 15.7

decisions per encounter, ear-nose-throat (ENT)-physicians and obstetrics and gynecology (OB/GYN)-physicians communicated significantly fewer decisions; 7.1 (p=0.006) and 11.0 (p=0.023) respectively. Compared to ENT-physicians, neurologists and pediatric physicians communicated significantly more decisions; 13.6 (p=0.029) and 13.4 (p=0.041) respectively. Besides internists and ENT-physicians, the remaining six groups of hospital specialists had on average between 11.1 and 13.6 decisions. Of the 628 "drug-related" decisions, 299 were found in the 121 internal medicine encounters, meaning an average of 2.5 (SD=2.3) "drug-related" decisions per encounter, compared to an average of 1.3 (SD=1.9) in the other specialties combined (p=0.002).

Figure 1 illustrates the average number of decisions communicated by each physician in their encounters (2-8 encounters per physician). The three physicians who averaged the highest (29.5, 23.5, 23.3 respectively) were women. The remaining physicians averaged between 6.7 and 20.5 decisions. The range of decisions per encounter varied substantially from physician to physician, the smallest range was 5 (9-14) and the largest was 29 (11-40).

Discussion

We set out to identify and classify all clinically relevant decisions communicated in 372 hospital encounters using the novel taxonomy DICTUM. (24) We found that patients, on average, were exposed to more than 13 medically relevant decisions per patient-physician encounter. The encounters in this study were representative of everyday activity in non-psychiatric clinical departments in a large Norwegian hospital. Across topical categories, decisions were diverse; although diagnostic decisions predominated, almost half were of other kinds. Across temporal categories, the majority of decisions were made in the present, but a substantial amount was brought into the encounter as new information, or presented as conditional, depending on future trajectories. With the exception of internal medicine and

ENT encounters, we found only minor differences among disciplines. Also, decision frequencies were not associated with patient or physician characteristics. The question is if this resemblance between specialties and physicians, could indicate that DICTUM captures a general structure of how decisions are communicated in medical encounters?

Observed differences, e.g. a higher frequency of preformed decisions in ward rounds, a lower total frequency in ENT encounters, more "gathering information" decisions in ER encounters and more "drug-related" decisions in internal medicine encounters, are all findings that could be expected from these different clinical contexts. WR encounters are commonly preceded by chart review, huddles or formal meetings where providers, either alone or as a team, make judgments and decisions without the patient present. ENT encounters commonly deal with only one concern. In ER encounters the diagnostic process is at its earliest and gathering additional information through tests or consulting with a colleague or a next of kin is what drives the process forward. Internists deal with more drug-related decisions, partly because their patients often have several previous medications in need of review and partly because diseases cared for by internists frequently have the potential for improvement or prevention through pharmaceutical therapy.

The difference between male and female physicians represents two decisions per encounter; however, this difference was not statistically significant and we are not convinced that the difference is of clinical significance. On the individual level, however, the averages and ranges of decisions varied greatly, also within disciplines. Illustrated by averages and ranges, respectively, Figure 1 shows large inter-physician and intra-physician variability: the first possibly reflecting each physician's communication style, and the latter possibly associated with the patient's communication style and the relevant clinical context.

One may challenge our definition of decisions. Previous studies of decisions in patient-physician encounters have reported substantially lower frequencies, varying between

on average three and seven decisions per encounter in five different studies. (15-19) Each of these studies have identified decisions with the aim of describing patient involvement in decisions. These studies did not include diagnostic decisions (comprised by our first three categories); if diagnostic decisions are subtracted from our material, our findings align with the findings from previous studies. The inherent elements of medical encounters that we have defined as diagnostic decisions, have in previous studies been framed as clinical questions that physicians attempt to answer. Ely et al. developed a taxonomy of clinical questions to assess how physicians deal with the challenges of treatment, choice of tests and also diagnosis, prognosis and etiology, by building their framework around clinical questions instead of the judgments and decisions that produce the answers. (34,35) DICTUM may help studies on how physicians and patients deal with and answer these clinical questions in dialogue.

A detailed and exhaustive description of clinical decisions, as they appear to patients in medical encounters, could aid clinical studies and assessments of real-life practice with normative or prescriptive aims. DICTUM offers the possibility of assessing all points in time where decisions are communicated. The basis of diagnoses, etiology, prognoses, care plans, follow-up, use of time and resources can all be scrutinized with a normative approach, on provider or system level. Additional relevant data would be necessary to distinguish between desired standard and substandard medicine. Such data, e.g. patient or physician surveys or interviews, patient chart reviews or peer review of encounters, could be collected at the time of decision-making but also followed up at a later stage. For inpatient care, an observation framework exceeding the duration of the patient-physician encounter could shed light on which and how decisions are made when the patient is not present – decisions that we in this study observe are presented to patients as information ("preformed decisions").

Introducing physicians and patients to the DICTUM taxonomy before a clinical encounter, might affect how decisions are made and communicated. Discussing the observed decisions with physicians and patients after the encounter, could provide insight into the lapses in comprehension, meaning and implications of the information shared during the encounter. Providers and institutions strive to deliver high quality care, increasingly focusing on evidence, patient preferences, safety, efficiency and use of resources. Raising awareness around which decisions need to be made, how they are made and who should make them, may not have causal effect on performance, but it would put the punctuation marks of care out in the open.

There are several limitations to our study. The study was conducted applying a novel taxonomy, that identifies and classifies clinically relevant decisions in a substantially broader way than previous studies describing the number of decisions in medical encounters.

The taxonomy has not been tested in general practice or psychiatric practice, nor in other hospitals than the one in our study. From an observer perspective, we could not always determine for sure whether the decision had been made before the encounter or was made there and then. In cases where we were in doubt, we coded the decisions as being made in the present. We have studied a videotaped material collected over a limited period of time.

Although there may be cultural differences varying over time, between hospitals, regions, countries and how health care is financed and legislated, we argue that the taxonomy captures a universal structure of how decisions are communicated in meetings between patients and physicians. Use in other settings is needed to further evaluate the taxonomy's applicability, reliability and validity.

Conclusion

Patient-physician encounters contain a larger number of clinical decisions than described in previous studies. Comprehensive descriptions of how decisions both as judgments and actions are communicated in encounters, may serve as a first step in assessing clinical practice with respect to efficiency and quality, on a provider or system level.

Footnotes

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Contributors: EHO and PG contributed equally to this study. PG conceived the study and put together the study group. EHO analysed the first 30 videos and selected statements to be discussed in the study group. EHO, JCF, ES and PG took part in all seven group meetings and all four independently analysed the 20 videos for inter-rater reliability measurements. Because of language barrier RMF did not part take in analysis of the videos, but transcribed and translated statements were presented to RMF during the analytic phase. EHO analysed 372 videos. PG analysed every 20th of these videos to check for inter-rater drift. EHO and PG analysed the data with simple descriptive statistics. JSB performed multi-level statistical

analyses. EHO, JCF, ES, RMF, JSB and PG analysed the data and reviewed the manuscript for its intellectual content. All authors had full access to all the data and take responsibility for the integrity of the data and accuracy of the analysis. EHO is guarantor.

Transparency declaration: EHO affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Table 1: The Decision Identification and Classification Taxonomy for Use in Medicine (DICTUM)

	Topical category	Category description	Example of statement conveying a decision
1	Gathering additional information	Decision to obtain information from other source than patient interview, physical examination and patient chart; ordering new tests/diagnostic procedures for the patient, actively seeking external information from other party (other hospital, general practitioner, family member etc) or discussing patient with other physician or health care personnel	"I am going to order an MRI of your skeleton"
2	Evaluating test result	Simple, normative assessments of clinical findings and tests	"Your blood pressure is high. 180/100 is high"
3	Defining problem	Complex, interpretative assessments that defines what the problem is and reflects a medically informed conclusion, thereby being either a diagnostic conclusion, an evaluation of state of health, an etiological inference or a prognostic judgment	"This is basically what we call osteoarthritis"
4	Drug-related	Decision to start, refrain from, stop, alter or maintain a drug regimen	"I will give you a four day treatment of dexametasone"
5	Therapeutic procedure-related	Decision to intervene upon a medical problem, plan, perform or refrain from therapeutic procedures of a medical nature	"We cannot operate more on you"
6	Legal and insurance-related	Medical decision concerning the patient, which is based upon or restricted by a legal regulation or financial arrangements	"I will write you a sick leave note"
7	Contact-related	Decision regarding admittance or discharge from hospital, scheduling of control and referral to other part of the health care system	"She is so weak that she should be admitted"
8	Advice and precaution	Decision to give the patient advice or precaution, thereby transferring responsibility for action from provider to patient	"You should stop smoking completely"
9	Treatment goal	Decision to set defined goal for treatment and thereby being more specific than giving advice	"We want to get the Alc down between 7 and 8"
10	Deferment	Decision to actively delay decision or a rejection to decide upon problem presented by patient	"You have to discuss this with your family doctor"
	Temporal category	Category description	Example of statement conveying a decision
A	Preformed	Decisions which have already been made and are brought into the encounter by the physician as information	"We have started you on some anticoagulants"
В	Here-and-now	Decisions made in the present	"I will get an ultrasound of your leg tonight"
С	Conditional	Decisions prescribing future actions given a certain course of events	"If the pills don't alleviate your pain, you may double the dosage"

Table 2: Characteristics of the physicians and patients in our sample*

		N (%)
Patients	Men	182 (49)
	Women	190 (51)
	Total	372 (100)
	Age 0-17	81 (22)
	Age 18-60	167 (45)
	Age >60	124 (33)
	Total	372 (100)
Physicians	Men	35 (60)
	Women	23 (40)
	Total	58 (100)
	Age <40	30 (52)
	Age ≥40	28 (48)
	Total	58 (100)
	Internal medicine (cardiology, respiratory medicine,	19 (33)
	nephrology, gastroenterology, endocrinology, hematology,	. ,
	infectious diseases, oncology)	
	Surgery (gastro surgery, urology, thorax & vascular surgery)	7 (12)
	Orthopedics	5 (9)
	Ear-nose-throat (ENT)	2 (4)
	Anesthesiology	3 (5)
	Obstetrics & gynecology (OBGYN)	6 (10)
	Pediatrics	8 (14)
	Neurology	8 (14)
	Total	58 (100)
Setting	Outpatient (OP)	291 (78)
J	Ward round (WR)	58 (16)
	Emergency room (ER)	23 (6)
	Total encounters	372 (100
The 372 pa	tient-physician encounters that was included in our analysis	,

Table 3: Distribution of decisions across ten topical and three temporal categories, number of encounters with different decision categories present, and averages per encounter.

	Topical category	N (%)	Present in number of encounters (%)	Average per encounter	Min- max
1	Gathering additional information	504 (10.1)	227 (61.0)	1.4	0-8
2	Evaluating test result	829 (16.7)	289 (77.7)	2.2	0-13
3	Defining problem	1512 (30.4)	355 (95.4)	4.1	0-18
4	Drug-related	628 (12.6)	223 (59.9)	1.7	0-10
5	Therapeutic procedure-related	260 (5.2)	142 (38.2)	0.7	0-7
6	Legal and insurance-related	90 (1.8)	68 (18.3)	0.2	0-4
7	Contact-related	496 (10.0)	288 (77.4)	1.3	0-5
8	Advice and precaution	397 (8.0)	205 (55.1)	1.1	0-8
9	Treatment goal	70 (1.4)	56 (15.1)	0.2	0-3
10	Deferment	190 (3.8)	129 (34.7)	0.5	0-5
	Total	4976 (100)	372 (100)	13.4	2-40
	Temporal category				
A	Preformed	797 (16.0)	213 (57.3)	2.1	0-22
В	Here-and-now	3534 (71.0)	371 (99.7)	9.5	0-31
C	Conditional	645 (13.0)	277 (74.5)	1.7	0-9
	Total	4976 (100)	372 (100)	13.4	2-40

Table 4. Distribution of topical and temporal decision categories in three different settings

		Outpatient	Ward round	Emergency room
Tota	al by topical categories N (%)	3905 (100)	812 (100)	259 (100)
1	Gathering additional information	368 (9.4)	66 (8.1)	70 (27.0) 1
2	Evaluating test result	683 (17.5)	100 (12.3)	46 (17.8)
3	Defining problem	1201 (30.8)	253 (31.2)	58 (22.4) ²
4	Drug-related	438 (11.2)	$154 (19.0)^3$	36 (13.9)
5	Therapeutic procedure-related	216 (5.5)	40 (4.9)	4 (1.5)
6	Legal and insurance- related	67 (1.7)	22 (2.7)	1 (0.4)
7	Contact-related	388 (9.9)	86 (10.6)	22 (8.5)
8	Advice and precaution	$324 (8.3)^4$	60 (7.4)	13 (5.0)
9	Treatment goal	60 (1.5)	7 (0.9)	3 (1.2)
10	Deferment	160 (4.4)	24 (3.0)	6 (2.3)
Tota	al by temporal categories N (%)	3905 (100)	812 (100)	259 (100)
A	Preformed	456 (11.7)	319 (39.3) 5	22 (8.5)
В	Here-and-now	2921 (74.8)	401 (49.4) ⁶	212 (81.8)
C	Conditional	528 (13.5)	92 (11.3)	25 (9.7)

Significantly higher than in outpatient (p<0.001) and ward round encounters (p<0.001)

² Significantly lower than in emergency room encounters (p=0.028)

³ Significantly higher than in outpatient encounters (p=0.031)

⁴ Significantly higher than in emergency room encounters (p=0.035)

⁵ Significantly higher than in outpatient (p<0.001) and emergency room (p<0.001)

⁶ Significantly lower than in outpatient (p<0.001) and emergency room (p=0.003)

Table 5. Average of decisions per encounter across gender, age, setting and specialty

	Average (95% CI)
Physicians	
Men	12.7 (11.9-13.5)
Women	14.7 (13.4-16.0)
Age <40	13.5 (12.5-14.6)
Age ≥40	13.2 (12.3-14.2)
Patients	
Men	13.2 (12.2-14.2)
Women	13.6 (12.6-14.5)
Age 0-17	12.4 (10.8-14.0)
Age 18-60	14.1 (13.1-15.2)
Age >60	13.0 (11.9-14.2)
Setting	
Outpatient clinic	13.4 (12.6-14.2)
Ward round	14.0 (11.9-16.1)
Emergency room	11.3 (9.1-13.4)
Specialty	
Internal medicine	15.7 (14.5-16.9)
Surgery	12.1 (10.4-13.8)
Orthopedics	12.6 (10.5-14.6)
Ear-nose-throat (ENT) ¹	7.1 (4.7-9.6)
Anesthesiology	11.1 (5.1-17.1)
Obstetrics and gynecology ²	11.0 (9.3-12.7)
Pediatrics ³	13.4 (11.2-15.5)
Neurology ⁴	13.6 (11.6-15.5)
1 Significantly lower than inter	

¹ Significantly lower than internal medicine (p=0.006)

Figure 1: Distribution of frequency of decisions in encounters for each physician. Diamonds indicate average of decisions per physician (inter-physician variability). The vertical lines indicate the range for each physician (intra-physician variability). One physician for whom we did only have broad consent for one video is not shown.

² Significantly lower than internal medicine (p=0.023)

³ Significantly higher than ENT (p=0.041)

⁴ Significantly higher than ENT (P=0.029)

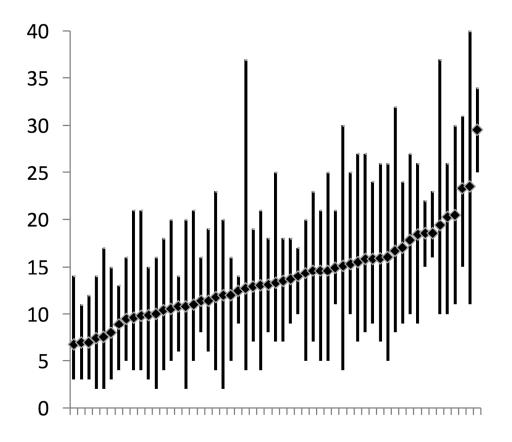


Figure 1: Distribution of frequency of decisions in encounters for each physician. Diamonds indicate average of decisions per physician (inter-physician variability). The vertical lines indicate the range for each physician (intra-physician variability). One physician for whom we did only have broad consent for one video is not shown.

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Appendix Table: Primary diagnoses coded in the 372 encounters according to International Statistical Classification of Diseases and Related Health Problems Revision 10 (ICD-10)

ICD-10 categories (classification letter)	N (%)
Diseases of the circulatory system (I)	50 (13)
Neoplasms (C/D)	38 (10)
Symptoms, signs, findings not classified elsewhere (R)	35 (9)
Diseases of the digestive system (K)	32 (9)
Diseases of the muscoloskeletal system (M)	29 (8)
Diseases of the genitourinary system (N)	28 (8)
Endocrine disorders (E)	27 (7)
Diseases of the nervous system (G)	25 (7)
Diseases of the respiratory system (J)	25 (7)
Pregnancy, childbirth (O)	18 (5)
Injury due to external cause (S/T)	16 (4)
Infectious disease (A/B)	14 (4)
Congenital malformations (Q)	8 (2)
Factors influencing health status and contact with health	6(1)
system (Z)	
Diseases of the ear (H)	5 (1)
Diseases of the skin (L)	4(1)
Diseases of the blood (D)	3 (1)
Mental and behavioral disorders (F)	3 (1)
Conditions originating in perinatal period (P)	3 (1)
Preoperative visit without known problem	3 (1)
Total	372 (100)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

For: "Clinical decisions presented to patients in hospital encounters: a cross–sectional study using a novel taxonomy"

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1, 2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5-8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-8
Bias	9	Describe any efforts to address potential sources of bias	Not done
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7-8
		(b) Describe any methods used to examine subgroups and interactions	7-8
		(c) Explain how missing data were addressed	No missing data
		(d) If applicable, describe analytical methods taking account of sampling strategy	Not applicable
		(e) Describe any sensitivity analyses	7-8

Results			
		(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8-9
		(b) Indicate number of participants with missing data for each variable of interest	Not relevant
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-11
		(b) Report category boundaries when continuous variables were categorized	8-11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-11
Discussion			
Key results	18	Summarise key results with reference to study objectives	11-12
Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias		14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	12-14
Other information		-//.	
Funding	unding 22 Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based		16

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.