Clinical Decision Science: Proof of concept

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ORIGINAL RESEARCH:

Clinical Decision Science: Proof of concept

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ABSTRACT   Clinical decision science, a newly identified area of scholarship, describes how clinical research is used for a patient, within the context of their unique social conditions. We hypothesize that physicians use sociocultural context as an important input to their decision making. We performed a prospective, randomized, double-blind mixed methods study. Family medicine faculty and residents at a community hospital family medicine residency were included in the study. After academic journal club discussing a primary research paper, physicians were asked if they would prescribe medication for a patient who was similar to the subjects in a research paper. However, social and cultural context was given to the cases. The physicians were block randomized into two groups; Group A was given a case with a patient who had a social and cultural context more conducive to lifestyle modification, while group B had a case more conducive to prescribing medication. Primary outcome was whether or not physicians prescribed medication, allowing for a 2x2 table for analysis. We also asked a free response question regarding the reasoning for their decision and performed qualitative analysis. In group A (n=14), no subjects prescribed medication. In group B (n=18), six subjects prescribed medication. (chi-square statistic with Yates correction 9.95, p=0.001). Thematic analysis in group A showed 22 statements related to medical practice or disease characteristics, and 25 statements related to familial relationships and patient preferences. In group B, subjects who prescribed medication made 30 statements related to medical practice, and 13 statements related to patient preference. Subjects who did not prescribe medication made 10 statements related to medical practice, and 1 statement related to patient preference. This study demonstrates social context of individual patients, together with evidence, affects clinical decision and management. We propose further study into how this affects physician decision making, a scholarly field we call Clinical Decision Science.

Keywords: *clinical decision science, social context, clinical practice*

Introduction

Despite the inherent complexity of clinical decision making, the process by which clinicians make decisions has only been studied on a sociologic level. Sociological research can only describe behavior of groups of physicians and cannot inform how an individual clinician generates a clinical decision.[1,2] Experimental research that takes patient, physician, and practice setting characteristics into account and is related to clinical problems encountered in day-to day practice does not exist.[3,4] Clark et. al. state "...focus on physicians' thinking has been accompanied by rather little attention to social context..."[4] Similarly, Bachur et. al. in a more recent paper note, "...literature that is focused on clinical practice...is almost nonexistent."[5]

The ideal of a biopsychosocial model of clinical practice has been proposed.[6,7] Although it may be achieved in clinical practice, it has never been studied in the medical literature. Although doctors excel in the biological domain and have some skills in the psychological domain, the role that a patient's social context plays in clinical practice has largely been ignored. This is understandable because physicians receive no formal training to assess social context.[8] Because physicians receive limited training

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to assess social context, it remains an important area for future research. There is a need for a scholarly discipline that examines the contribution of the patient's social context to clinical decision making.

Clinical Research in Practice: Journal of Team Hippocrates has published reports within this domain, which it has labeled clinical decision science.[9] Clinical decision science is "a holistic examination of how clinical decisions are made. This includes both biomedical and medical social sciences, in addition to other ways of understanding human experience."[10]

This research report is the first randomized controlled trial demonstrating that social context changes clinical decisions. Our hypothesis was that physicians' prescribing behavior is influenced by social context of the patient.

Methods

This was a prospective, randomized, double-blind, mixed methods study. We obtained IRB approval.

Prior to initiating the study, a power analysis was done. We purposefully created extremes in descriptors of the patients' social context to achieve the greatest effect size possible between two standardized clinical scenarios. This was in keeping with the "proof of concept" purpose of the research and the limitation we had on total number of possible cases. Using an alpha of 0.05, beta of 0.2 (Power of 80% to detect a difference) and a 50% effect size between the two groups, the study required 13 participants in each group.

The study was performed in a family medicine residency at a community hospital. Participants included faculty and residents who attend journal club. A list of all faculty and residents was obtained from the program coordinator. We excluded faculty and residents who were study investigators.

At our institution, Journal Club is focused on learning to critically appraise clinical research. For this study, the paper that was critically appraised and the surveys about clinical decisions were thematically linked—meeting the standard of "Clinical Research in Practice". The critically appraised clinical research paper compared lifestyle modification versus metformin for patients with impaired fasting glucose.[11] For a brief description of the Journal Club paper and the salient points discussed, see Appendix A.

Prior to journal club, study materials were distributed to all potential participants in a sealed envelope. Potential participants were instructed not to open the envelope until after journal club.

Verbal recruitment and consent using an IRB-approved Information Sheet were explained by one of the investigators (AN). Participants were stratified by year of practice and then randomized into two groups with a block four design. Each of the two groups was assigned a standardized, written patient case. Both standardized cases had identical biomedical facts, but markedly different social contexts. The contrasting social contexts used the parameters of familial support, patient preferences, emotions, institutional constraints, and patient reported conversations.[12] In group A, the social context favored lifestyle modification. In group B, the social context favored pharmacotherapy.

The social context of the patient in the standardized case comprised the independent variable. Included with the patient case was a survey, asking if the participant would prescribe medication (metformin) to the patient depicted in the standardized clinical scenario and additionally to describe their medical reasoning for that decision. The decision to prescribe or not prescribe medication was the dependent variable. The clinical scenarios and surveys are represented in Appendices B & C.

Immediately after the journal club discussion, participants opened the envelopes containing the research information sheet, written standardized patient case details, and the data collection survey. Participants were given ten minutes to read the materials and complete the survey. After finishing, participants placed their survey in an inner envelope marked, "ANONYMOUS & CONFIDENTIAL" and then sealed the inner envelope themselves. Participants then placed the inner envelope into another sealed envelope. If attendees wished to decline participation anonymously, they were instructed to place a blank survey in the inner envelope. The outer sealed envelopes were labelled with the participants' name, so that a response rate could be calculated. However, the inner envelope and survey, did not contain any identifying marks or information and participants were instructed not to put identifying information on any research material. The envelopes were collected by investigators, who calculated the response rate. The

envelopes were then given to a trusted agent. The trusted agent process was requested by the IRB and was a person that has no influence over respondents; this was to minimize coercion because the respondents included trainees. The trusted agent opened the outer envelopes and removed the anonymous and confidential inner envelopes, and immediately mixed them to maintain anonymity and confidentiality. In this way, no individual survey could be linked to any individual participant or attendee, whether they participated or declined participation.

The inner envelopes were then opened, and data was collected and analyzed. The decision to prescribe medication was recorded as a dichotomous dependent variable, allowing a 2x2 table, comparing social context to medication prescription behavior. The free response section asking participants to explain their decision was analyzed using content analysis and thematic analysis. All the investigators participated in the analysis and developed a consensus when applying labels to the qualitive data. Content analysis was done by pile sorting identical or nearly identical responses. Thematic analysis was done by applying a label describing a collection of related content items.

Results

A total of 38 potential participants were identified. We received 33 responses, and 1 response was blank indicating non-participation. In total, we received 32 completed surveys, for a response rate of 84%.

In group A (social context favoring lifestyle intervention), 0/14 subjects prescribed metformin to the patient. In group B (social context favoring medication), 12/18 subjects prescribed metformin to the patient. Using Fisher's exact test, this was statistically significant with p=0.0001. (Chi-square statistic with Yates correction 9.95, p=0.001)

Figure 1 shows the labels applied by the investigators summarizing the qualitative responses explaining participant prescribing behavior. Many respondents recorded more than one rationale. Table 1 gives the specific content with frequencies in Group A. Table 2 gives the specific content with frequencies in Group B.
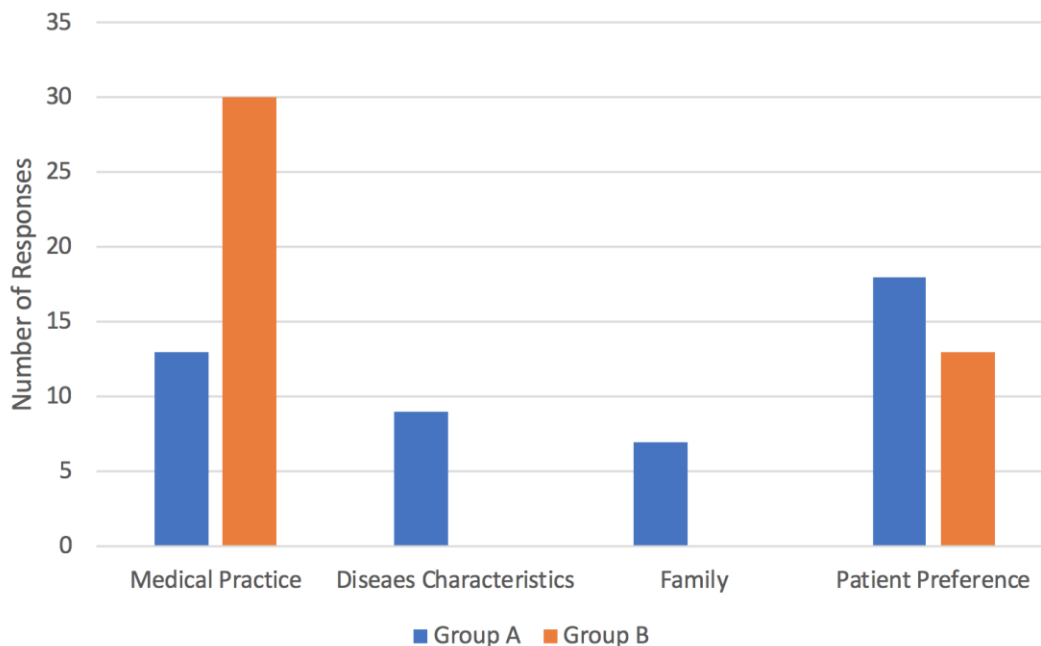

Figure 1. Content analysis of rationales for prescribing behavior

Table 1. Content analysis for Group A (Social context favoring lifestyle intervention)

Category Labels	Categories	Frequency	Exemplars of Categories
Medical practice (N=13)	plans follow up	3	I would set a specific goal…(3 to 6 months)…I would approach [medicine] if no progress is made
	compliance expected	2	Patient has serious verbalized misgivings about med and therefore likely won't take it even if I Rx it.
	evidence	2	Evidence shows this is more effective than metformin
	protocol/guideline	1	Lifestyle is better in prevention
	side effects of medicine	1	No change in mortality and morbidity while increase side effects and polypharmacy
Disease Characteristics (N=9)	non-severity of disease	6	The patient has a borderline elevated A1c, so it is not very high
	co-morbidity	3	…Diet and exercise…would help his other medical problems
Family (N=7)	support (wife)	5	[The patient] has a support system to change lifestyle.
	relationship with wife	1	Diet and exercise…. could help his relationship with his wife
	self-worth	1	Diet and exercise could help…his own feelings of self-worth…
Patient preference (N=18)	patient motivation	9	He is motivated to try lifestyle modification…
	patient preferences	7	[Patient] expresses motivation for lifestyle modification over metformin
	past experience	2	…Good past experience with exercise that is encouraging.

Table 2. Content analysis for Group B (Social context favoring medication)

Category Labels	Categories	Frequency	Exemplars of Categories
Medical practice (N=30)	efficacy	7	I would give him metformin--low side effects and good outcome.
	noncompliance expected	4	Patient admits he won't make lifestyle changes
	family history	4	Based on patient's personal and family history, he is at high risk to develop diabetes.
	past treatment failure	4	He has already tried lifestyle modification without benefit.
	side effects of medicine	3	Starting a medication such as metformin has side effects (namely GI)…
	obesity	2	I would start him on metformin given his obesity and high-risk family history.
	evidence	1	There is no long-term evidence for decreases in morbidity and mortality when treating with metformin in the prediabetic range.
	follow up	1	I would want to keep close follow-up with him, watching his weight and blood sugars for improvement.
	chronicity	1	It sounds like this patient has had prediabetes for quite a while.
	natural history of disease	1	He is at high risk to develop diabetes.
	doctor patient relationship	1	I think you need to compromise at this point.
	beneficence	1	I would want to help him in a meaningful way…
Patient preference (N=13)	motivation	6	…He is motivated to avoid diabetes…
	patient preferences	4	If patient is not motivated to exercise and eat right, I won't change their mind.
	past experience	3	He has tried to make changes many times.

Thematic analysis in group A showed 22 statements related to medical practice or disease characteristics, and 25 statements related to familial relationships and patient preferences. In group B, subjects who prescribed medication made 30 statements related to medical practice, and 13 statements related to patient preference. Subjects who did not prescribe medication made 10 statements related to medical practice, and 1 statement related to patient preference. Group B was the only group where a prescription was given—one of the noteworthy findings of this study.

Results

Although this is a small pilot study, our data document a "proof of concept" that physicians include social context of the patient when making clinical decisions. This finding is a core tenet of Clinical Decision Science.

Weaver, et. al. demonstrated "a difference between the scholarly domains of clinical decision science and evidence-based medicine."[12] Various authors[4,12,13] have identified social factors important to the domain of clinical decision science. These factors include:

- conversations
- institutional structures
- emotions
- social determinants of health
- patient values and preferences
- family and personal relationships
- cognitive ability
- motivation
- social support
- interest
- normative expectations

As the field of clinical decision science matures all these categories should be kept in mind for designing future research.

We perceive an educational focus on biomedical facts and algorithms. However, the process of clinical decision making is complex and influenced by each patient's social context. Unfortunately, clinicians are not explicitly taught how to do this, and they must learn by observation in an apprenticeship learning environment. Academic focus on clinical decision science can expedite learning this important aspect of clinical practice.

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Appendix A: Journal Club Synopsis

Knowler W, Barrett-Connor E, Fowler S, et al. Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002 Feb 7;346(6):393-403.
https://doi.org/10.1056/NEJMoa012512

This multi-center trial enrolled 3234 prediabetic patients and randomized them to Placebo, Metformin, or Intensive Lifestyle Modification Program. Table 1 demographics indicated randomization was successful. Only the metformin and placebo group were double blinded. Both groups received standard dietary and exercise education comparable to our own clinical practice.

The intensive lifestyle group received a 16-lesson curriculum covering diet, exercise, and behavior modification in one-to-one sessions with case managers that was flexible, culturally sensitive, and individualized. This was followed by monthly individualized or group sessions to reinforce behavioral changes. Participants in our Journal Club acknowledged that this intervention was not feasible in our practice setting.

Over three years, the incidence of developing diabetes was 28.9% in the placebo group, 21.7% in the metformin group, and 14.4% in the Intensive lifestyle group.

Adverse events were mostly gastrointestinal symptoms, reported in number of events per 100 person-years. They were 30.7% in the placebo group, 77.8% in the metformin group, and 12.9% in the Intensive Lifestyle group.

The study was stopped early by the data safety monitoring board because a clear difference was demonstrated. Although funded by the NIH, one of the writing group owns stock in Bristol-Myers Squib, which sells metformin in the United States.

Appendix B: Group A (Social context favoring lifestyle modification) Survey

Pretend you just saw a 53-year-old man* in your clinic with a BMI of 34 and an A1c of 5.9 (normal<5.6). After counselling about his health, he tells you the following:

"Hey Doc, thanks for sharing all the information. I never liked pills. It scares me to put some foreign chemical in my body; who knows what's going to happen? I had a friend at work that tried that medication and he told me the diarrhea was horrendous. I don't need problems like that. I know I'm older and have gained weight but back in high school I was an athlete. I felt really good back then and I wouldn't mind trying to get back into shape. If I was in better shape my blood pressure and pulse would be better and that would help on my Department of Transportation physical. It would require me to change my diet, but my wife is vegan so at least I'd make her happy even if I was miserable. She's been nagging me to eat healthier and this just might give me the motivation for us to work on it together."

Do you write a prescription for metaformin at this visit?

_____yes   _____no

In your own words, please describe what you were thinking and how you decided to make your medical recommendation:

Thanks!

*Although we recognize gender equity, for the purposes of this research, we minimized confounding variables.

Appendix C: Group B (Social context favoring medication) Survey

Pretend you just saw a 53-year-old man* in your clinic with a BMI of 34 and an A1c of 5.9 (normal<5.6). After counselling about his health, he tells you the following:

"Hey Doc, thanks for sharing all the information. You pretty much told me what my last doctor said. I guess it's time for me to get serious. My dad and three of my four grandparents had diabetes and I saw what happened to them. I don't want my leg cut off like dad or wind up on dialysis like grandpa. That terrifies me. My problem is I don't like to exercise. Quite frankly I don't have the time because I'm busy at work. I can't see myself going to a gym and I'd wind up just wasting my money. I've tried to lose weight about 20 times in my life so far and it never works. I just need to get my blood sugar down quickly because every two years I got to get my blood drawn again to qualify for my life insurance. I need something with immediate results."

Do you write a prescription for metaformin at this visit?

_____yes   _____no

In your own words, please describe what you were thinking and how you decided to make your medical recommendation:

Thanks!

*Although we recognize gender equity, for the purposes of this research, we minimized confounding variables.