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## **Clinical Decision Science suggests different research questions need to be asked related to informed consent**

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## REFLECTION ON CLINICAL DECISION SCIENCE: Clinical Decision Science suggests different research questions need to be asked related to informed consent

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In the article, “Non-ST-segment elevation acute coronary syndrome: Early versus delayed cardiac catheterization” by Colleli et al. published in *Clinical Research in Practice, the Journal of Team Hippocrates*<sup>1</sup>, the authors describe a patient who had an NSTEMI and as the question of whether early cardiac catheterization compared to delayed catheterization provides a mortality benefit. They report that the patient said, “The doctor came in and told me to sign this paper because I needed a heart test.” Informed consent is a conversation, not signing a piece of paper. The authors suggest that an informed consent process that outlines the risks and benefits of early cardiac catheterization versus optimal medical therapy should be presented to the patient.

Despite the lack of evidence for significant benefit of early intervention for NSTEMI, it is not evident that the possibility of medical management is suggested to the patient in most cases.

I work at a hospital that has several practicing cardiologists. I had a series of hallway conversations with my cardiology colleagues to understand their perspective of why early invasive procedures continue to be performed almost universally on patients presenting with NSTEMI. One interventionalist said that he felt that most patients would opt for early intervention given that one study did show some evidence that early intervention resulted in increased survival at 5 years<sup>2</sup> (although this was not statistically significant). He did acknowledge that although he personally performed a thorough informed consent procedure (including presenting benefits, risks, and alternative procedures) that perhaps not all cardiologists obtained a thorough informed consent. Another cardiologist expressed his opinion, “Most patients presented with this data would opt for early intervention.” I wondered how he could ascertain that without asking the patient. At the very least there is likely a significant variation in the method in which informed consent is obtained, including timing (such as 1 day prior to procedure versus minutes prior to procedure), and the person obtaining consent (directly by the cardiologist versus by a PA or nurse). Yet another variable is how emphatic the doctor is when presenting the evidence and whether there is a personal bias by the physician during the informed consent process.<sup>3</sup>

My question is whether there is evidence that any particular type of informed consent would help guide patients in their decision to undergo early cardiac catheterization versus delayed catheterization. This is an important part of the new scholarship of Clinical Decision Science.

I performed a PubMed search for articles containing the key words “cardiac”, “catheterization”, and “informed consent”. Over 120 articles were found and the titles and abstracts were scanned for articles published in the last 20 years that directly analyzed the adequacy of the informed consent process for adults undergoing cardiac catheterization. One report was excluded as it was written in Italian. After I scanned the abstracts, five articles were identified that directly looked at the informed consent process for cardiac catheterization.

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In one article, “Education, and obtaining of informed consent, using multimedia before adults with congenitally malformed hearts are submitted to transcatheter interventions” by Rigatelli et al.<sup>4</sup>, the investigators compared use of written materials and a standard interview versus using multimedia approach with a booklet and a film for the informed consent procedure and found reductions in anxiety and heart rates in the group receiving informed consent using multimedia. This resulted in more sedation being required in the group that did not use multimedia for informed consent. These results are counterintuitive. The whole point of Clinical Decision Science is that it attends to the social context of an individual patient. It means identifying the patient’s anxieties and responding to them. Clinical Decision Science (CDS) presumes that patients are individuals and the informed consent process should be tailored to the specific needs, values, and social situation of an individual patient. Thus, when the authors compared “standard interview” versus printed material, they excluded a conversation with a compassionate physician that treats the patient as an individual. From the perspective of Clinical Decision Science, the research question is flawed.

In another article, “Converting the informed consent from a perfunctory process to an evidence-based foundation for patient decision making” by Arnold et al.<sup>5</sup>, the authors investigate the use of a web-based program to facilitate the informed consent process. The web-based PREDICT form was compared to a standard paper form. PREDICT forms used algorithms to calculate patient specific rates of complications. The use of PREDICT forms were associated with improved patient education and reduced anxiety. The title of this article implies that current clinical practice includes “perfunctory process” for informed consent. Again, Clinical Decision Science suggests a completely different process should be considered.

In a third article, “Effectiveness of video-based patient information before percutaneous cardiac interventions” by Steffenino et al.<sup>6</sup>, the authors investigate the effectiveness of using videos to enhance patient education for patients undergoing cardiac catheterization. The study shows that use of video enhanced patient knowledge of the procedure. CDS assumes that patients have other individual needs than simply “knowledge”.

In a fourth article, “Shared Decision-Making in Femoral Versus Radial Cardiac Catheterization” by Schwarzman et al.<sup>7</sup>, the authors analyze the ability of patients to make an informed decision to choose between radial versus femoral cardiac catheterization. The authors found that patient demographic factors (such as education and race) influenced their ability to understand procedure risks and make informed decisions.<sup>8</sup> The authors also suggest that patients generally prefer to defer the decision to physician. CDS suggests that the doctor who assumes this responsibility knows the patient well enough to use substituted judgement.

In a fifth article, “Discerning quality: an analysis of informed consent documents for common cardiovascular procedures” by Shahu et al.<sup>9</sup>, informed consent documents for cardiac procedures including cardiac catheterization were analyzed for various factors including legibility and explanation of procedure risks, benefits and alternatives. The authors found that for cardiac catheterization only 49% of the informed consent documents were considered legible, only 68% mentioned any procedure specific risk, and 0% mentioned any benefits or alternative procedures. The authors however did not investigate how the documents lack of information or legibility impacted patients.

Of note one abstract was found describing a research project to investigate why cardiac catheterization is being overused in stable coronary disease.<sup>10</sup> The study aims to investigate different influences on the overuse of cardiac catheterization including patient education and decision-making.

Based on the given information, it appears that informed consent overall improves patient satisfaction and education. It is also clear that the informed consent process is heterogeneous and that likely often fails to appropriately present risks, benefits and alternative therapies in a timely fashion. Doctors involved in the consent process should ensure that patients are presented with appropriate information in an unbiased and timely manner. Clinical Decision Science suggests that informed consent should be tailored specifically to the individual patient’s needs, not only by having them sign a document but also by speaking with the patients about their values, fears, and other aspects of their social situation. Speaking to patients with compassion and empathy while understanding their personal goals and desires would probably result in more patients towards electing non-invasive measures for treating NSTEMI.

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