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Chemical Engineers' Experiences of Ethics in the Health Products Industry

Ms. Dayoung Kim, Purdue University at West Lafayette

Dayoung Kim is a Ph.D. Candidate in Engineering Education at Purdue University. Her current research interest centers on engineering ethics and social responsibility, and she is specifically interested in cultural influences on engineers' moral formation. She earned her B.S. in Chemical Engineering at Yonsei University (Seoul, South Korea) in 2017 and M.S. in Chemical Engineering at Purdue University (West Lafayette, USA) in 2021.

Dr. Alison J. Kerr, University of Illinois Urbana Champaign

Alison Kerr received a doctoral degree in Industrial-Organizational Psychology from The University of Tulsa. Her research interests include training development and evaluation as explored across a variety of academic disciplines and organizational settings. She is currently assisting on a number of training projects aimed at developing engineering students on relevant non-technical professional skills including ethical practice and presentation.

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Abstract

While ethics education for chemical engineers has been emphasized, potential misalignment between the content of current ethics education and engineers' actual practice has been pointed out. To help improve ethics education for chemical engineers, this research-to-practice paper presents six descriptions of engineers' experiences related to ethics. The descriptions were constructed based on in-depth interviews with six chemical engineers who are currently working in the health products industry. As the descriptions provide evidence that ethics is pervasive in chemical engineers' daily practices, we argue that chemical engineering curriculum should include instruction relative to professional ethics in actual practice. This paper concludes with a discussion on potential ways to utilize these descriptions in ethics education.

Introduction

The American Institute of Chemical Engineers (AIChE) emphasizes ethical practice of their members by stating in the AIChE Code of Ethics that members shall "hold paramount the safety, health, and welfare of the public and protect the environment in performance of their professional duties" [1]. This is similar to other professional engineering societies including the National Society of Professional Engineers. Aligned with such codes of ethics of various professional societies and broader societal needs, ABET has included "an ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments" [2] as a required student outcome for engineering programs. However, while there have been continuing endeavors to include ethics in undergraduate chemical engineering programs in the U.S., chemical engineering faculty members often report insufficiency of ethics education in chemical engineering programs [3].

Considering the insufficiency and potential misalignment between current ethics education and engineers' actual practice, to help improve ethics education for chemical engineers, this paper introduces the chemical engineering component of a broader research project we have worked on. In that project, we have investigated practicing engineers' various ways of experiencing ethics in the health products industry [4]. While chemical engineers work in various industries which span from the oil and gas industry to food industry, we specifically focus on the health products industry in this paper because of the special public demands of ethical engineering practice towards the health products industry: Public demands ethical engineering practice of the health products industry specifically, because their products directly impact people's lives [5].

This research-to-practice paper illustrates the ethics-related experiences described by six chemical engineers who are working in pharmaceutical and medical device firms to provide chemical engineering educators with better ideas about ethical issues that chemical engineers might encounter in their workplaces. Given the richness in the interview data we collected, we expect that sharing a collection of these anecdotal experiences with chemical engineering faculty members will support the development and delivery of better aligned engineering ethics education

for chemical engineering students. We hope the descriptions of experiences can serve as useful resources which faculty members may utilize to discuss ethics in their classrooms and thus contribute to incorporating ethics education throughout chemical engineering curriculum. We suggest these specific educational implications in the discussion section of this paper.

Literature Review

Ethics education in chemical engineering

While there has been no strong consensus on how to teach engineering ethics for chemical engineering students nor on what the contents of the teaching should be, chemical engineering educators have endeavored to include ethics in their classroom instruction. In this section, we summarize previous efforts to teach ethics in chemical engineering community with a focus on three domains of teaching – content (what to teach), pedagogy (how to teach), and curriculum models (where to teach).

Content. Chemical engineering educators have touched on various topics related to ethics in their classroom. Ethical issues in engineering have included microethical issues, which involve issues in individual engineers' daily practice such as conflict of interest, and macroethical issues, which involve issues beyond the scope of an individual or an organization such as societal impact of technology [6]. Chemical engineering ethics education, like engineering ethics education in general, has primarily focused on teaching microethical issues, but some chemical engineering educators have introduced materials for teaching macroethical issues as well [7], [8] especially as issues like sustainability become to be more emphasized in chemical engineering process industry [9].

To gain further understanding of the current domain of chemical engineering ethics education, Bielefeldt and her colleagues [3] surveyed 107 chemical engineering instructors across 76 institutions in the U.S. to investigate faculty members' perceptions of education for ethics and societal impact of engineering. They reported that common topics that were covered in chemical engineering ethics education include safety, professional practice, engineering decisions under uncertainty, environmental protection, and sustainability. Although details and qualities of the instruction would vary depending on the instructor and institution, such faculty perceptions seem to support the need for broad topic coverage including micro- and macroethical issues in chemical engineering education.

Pedagogy. Bielefeldt and her colleagues discussed that according to chemical engineering faculty members, case studies are frequently utilized to teach ethics [3]. Case studies are one of the most popular methods to teach engineering ethics in general [10]-[12], and there have been various cases across different engineering disciplines [13] and cases span from historical disasters to cases which deal with issues that engineers are more likely to encounter in their daily practice [12] as well as positive ethics exemplar stories [14]. Ostensibly, there have also been endeavors to make and implement chemical engineering-specific case studies for chemical engineering students [13], [15], [16] including the famous example of The Union Carbide Pesticide Plant in Bhopal [15]. As a specific example, Watters et al. [17] introduced a stand-alone 2 credit ethics course for fifth-year

chemical engineering students which utilizes videos and case studies including both historical and current cases.

However, Borsen et al. [18] pointed out insufficiency in teaching materials for teaching ethics in chemical engineering context and argued that the development of case studies specifically for chemical engineering students could help engineering ethics instruction become more widespread in the chemical engineering discipline. Although historically there has been a limited amount of materials for teaching chemical engineering ethics, several cases have been and can be made with various topics and purposes. Addressing this issue, Shallcross and Parkinson [19], [20] published fictional case studies for chemical engineers which dealt with ethical issues including whistleblowing, loyalty to one's company and client, conflict of interest, and professional honesty and integrity. To further support the development of ethical engineering cases, Byrne, based on his teaching experience, [7] encourages the use of cases which are more immediate and relevant to students, because when he implemented disaster case studies for an introductory chemical engineering course, the results seemed too "remote and unlikely to students" [7, p. 237].

Curriculum models. Besides the pedagogical approach, various curriculum models for engineering ethics education have been discussed, including stand-alone ethics course and across-the-curriculum models [11]. Bielefeldt and her colleagues [3] showed that the most common setting where ethics is taught is senior capstone design classes, according to chemical engineering faculty members. However, even though the stand-alone ethics course is a common form of teaching ethics, Ocone [21] argued that introduction of ethics throughout the whole curriculum would be necessary, because an integration approach has the advantage of integrating ethical issues into technical coursework, as Watters et al. [17] also pointed out. As an across-the-curriculum model, Davis [22] suggested a micro-insertion approach, which introduces small units of ethics into technical courses. We will discuss this approach and how this paper's work might be integrated into this approach in more detail in the discussion section.

Insights from the industry for ethics education

The workplace provides engineers with opportunities to encounter and experience ethical issues. McGinn [23]'s survey with practicing engineers indicated that most (80.2% in 2001 survey, 89.2% in 1999 survey, and 84.4% in 1997 survey) practicing engineers think engineering students are likely to encounter ethical issues in their future engineering practice, and therefore they should be exposed to ethical issues during their formal engineering education (92.2% in 2001 survey, 93.8% in 1999 survey, and 92.6% in 1997 survey). As various ethical issues arise in engineers' workplaces, individuals will likely have opportunities to actually perform in ethical or unethical ways. Notably, Moore et al. [24] pointed out that since organizations have hierarchical nature in general, employees can be easily pressured to engage in unethical behavior in workplace setting.

As engineers encounter unique ethical challenges in the industry, it has been argued that engineering ethics education can be improved through direct conversation with engineers working in the industry [25]. Aligned with this argument, studies have focused on practicing engineers to draw implications for engineering ethics education. For example, Brightman et al. [4] conducted a phenomenographic study to understand engineering practitioners' different ways of experiencing

ethics in engineering to better align engineering ethics education with actual experiences related to ethics which engineers actually encounter in their workplaces. Kim et al. [26] also investigated what incidents engineering practitioners encounter in their workplace broaden their understanding of ethics in engineering. Beyond those, Hess et al. [27] investigated how engineering practitioners conceptualize empathy and care and in what ways empathy and care exist in their practice. Despite there having been a few studies which specifically focused on engineering practitioners to better understand their daily practices and improve engineering ethics education, there are still fewer studies which have focused specifically on practicing *chemical* engineers and the relevant need for ethics education for chemical engineering students.

Methods

Data collection

This paper focuses on the chemical engineering component of a broader research project in which we have investigated practicing engineers' ways of experiencing engineering ethics in the health products industry [4]. In this broader work, we conducted in-depth semi-structured interviews with 43 engineering practitioners to elicit their specific experiences related to ethical engineering practice.

The interviews included four parts: (1) Background, (2) Experience(s), (3) Conceptual, and (4) Summative. Part (2) comprised the bulk of the interviews as an interviewer asked each participant to share some examples of their experiences with ethical engineering practice. Each experience began with the high-level question, "Can you describe an experience you have had with ethics in engineering?" This question was followed by an intensive set of follow-up questions, such as "What was your role in the situation?", "Who else was involved in this situation? What were their roles?", and "How did you approach the situation? Please walk me through the experience." After fully detailing the first example, the interviewer asked the participant if they had additional examples. Then in Part (3), the interviewer asked questions to understand the participant's conceptual understanding of ethics, such as "Based on what we have discussed, what would you say ethical engineering practice is?"

Of the 43 participants, six had a chemical engineering background. This paper focuses on the experiences described by these six chemical engineers practicing in pharmaceutical and medical device companies in the health products industry. Participant demographic information is minimized for the six-participant sample to maintain confidentiality. Of the six participants four identified as male and two as female. They had between 6 and 32 years of engineering experience and worked in areas of research, product development, manufacturing, and project management.

Development of summary and description of experiences

For this paper, we developed a 100-word summary and longer description for each of the six chemical engineers. Those were developed based on the experiences they shared during their interviews. Because we are involved in the larger research project, this was not our first time engaging with the participant interview transcripts. However, for this specific study we did re-read all the transcripts and did approach this study as an independent project. For each of the six

participants, while re-reading through the interview transcripts, we made notes around the general themes that we each thought best represented the nature of the interviewees' experiences. We also took notes around specific passages and phrases that captured these themes.

For each participant, we met and shared our individual notes and theme interpretations and discussed any similarities and discrepancies. Then, we took turns writing an initial rough summary of each of the participants' main themes. We then reviewed the other researchers' summaries to align our approach to the summary writing. After we had done this for all transcripts, we then took turns with writing more thorough descriptions of experiences for each of the participants which we again reviewed and revised based on each other's feedback. At times, we also discussed our interpretations with an additional member of our larger team. The following is the refined summaries and descriptions from our in-depth review of the ethical engineering experiences of the six chemical engineers interviewed.

Results

In this section, we present the overarching summaries of how each engineer experiences ethics followed by more detailed descriptions for each of the six participants. Table 1 provides the summaries of each participant's way of experiencing ethics and provides an overview of the core elements of their experiences.

Table 1. Summary of each interviewee's ways of experiencing ethics

Pseudonym	Way of experiencing ethics
James	For James, ethical engineering practice is about honesty and transparency and being thorough with technical procedures. The quality of the work you do matters, and it needs to be thorough, detailed, and accurate. More precisely, ethical engineering is also about *how* you do the work such that you are knowledgeable, do not take shortcuts, and comprehensively conduct and report all procedures and research results needed to ensure the safest and most effective product. It may be necessary to voice concerns if you have additional thoughts, information, or questions about the quality of the product or the testing of the product.
Cooper	For Cooper, ethical engineering practice is following the right rules and procedures even if you are not being observed. Also, recognizing a culture of interdependence, Cooper expresses that other people can help ensure that the rules and procedures are followed by all. To be ethical means being proactive in ensuring that rules and procedures are followed both by yourself and others. For example, if you make a mistake or find something goes wrong, you should speak up honestly so that corrective action or future preventative action can be taken. It is important to recognize the greater purposes behind ensuring safety and quality and to also trust that a rule or procedure is established consciously. Making these ethical practices unconscious is also often helpful. Finally, Cooper identifies that there should be no falsification of data in testing.
Mustang	For Mustang, ethical engineering practice is primarily working with personal integrity and doing work in ways that will preserve your pride and reputation which includes being honest and fair. Engineers are data-driven, so when

	dealing with data, it should be presented transparently and with respect to the context in which it was taken. It is important to capture and report data with honesty and accuracy. Furthermore, when documenting, it is important for the engineering to make sure the full story is represented and told.
Carpathian	For Carpathian, ethical engineering practice is actively considering both benefits and risks to the patient. Patient-forward thinking is important, and products should improve health outcomes. Whatever work engineers do should also be geared towards improving the overall state of society as much as possible. Therefore, developing a drug whose performance would be sufficient across various populations is what needs to be pursued. Since engineers are not operating in a vacuum, the work they do always has an impact and therefore has an ethical foundation and implication. Also, when making decisions with colleagues, the arguments used should be based on scientific rigor.
Taz	For Taz, ethical engineering practice is about endeavoring to comply with norms and established standards of engineering practice. Taz also recognized that engineering ethics also includes being aware of how conflicts may exist which may impact the decisions about or the ability to follow these standards. This means ethical engineering practice includes awareness of what factors may lead to lack of compliance such as interpersonal dynamics, consideration for the implications and repercussions from violating expected norms or standards (e.g., damage to your reputation), and making decisions about a course of action.
Angela	For Angela, ethical engineering practice consists of two main aspects. First ethical engineering practice is making decisions in the interest of the customer, which includes but may not be limited to patients. The second aspect of ethical engineering practice is to recognize that others may be able to contribute in meaningful ways. As an additional note, modeling these aspects (especially as a leader) is also part of ethical engineering practice.

Each interviewee's detailed experiences are described in the following subsections.

James

As a research engineer, the first example James gave of an experience with ethical engineering was about determining and conducting essential tests. James explained that his work involves consulting or working with other sponsors and said, "we would get a project, we'd work on it, we'd present our results, and give recommendations". The example James shared as related to ethics was of an instance when the sponsor wanted to do something that would have bypassed certain tests that he and his team felt should be conducted. James explained,

> I can think of one instance where, what, or the sponsor was trying to do, or what the decision our sponsor came with wasn't something that I agreed with. And talking to others in my team, who worked on that project, we didn't agree with that, either. And so, it became more of trying to convince that person, this is more of the right thing to do.

He explained why the tests he and his team wanted to conduct were important:

> They're important because they kind of give you ideas, give you a better understanding of the safety of the device […] It wasn't necessarily required by law, if that makes any sense, but it was just something that we felt was necessary. Because the test, the things that we had done, they were still, we felt there were still more questions about safety. And that's something that, we felt like these certain tests should be performed.

Here, James emphasized ethics and law are not the same: Ethics sometimes requires more than compliance with the law. He explained that he was the person who raised the concern in a meeting with the sponsor but that ultimately, he wasn't in a leadership position so that was the extent of his responsibility and influence with this ethical concern.

> I was the one that raised the concern. Just because, I mean, we were in a meeting, and the project leader said, or the project sponsor said, 'This is what we plan to do.' I just raised my concerns […] I didn't have any leadership responsibility in the project, per se. But I was just in a meeting and voiced my concern.

In addition to identifying and communicating the need for important tests, James also gave several additional examples which emphasized that ethical engineering includes transparency, decision-making, and proper reporting. These examples were less detailed and presented more as a run through of different ways he has experienced these aspects in his career. One example was during his time as a postdoc when made decisions about using animal subjects in research. He said,

> A lot of the considerations were: is now the correct time? Is our project farther, is it along far enough that we're ready for an animal study? You know, number one. Two: what are we trying to get out of this? Do we really need, just throwing out an example, do we really need 100 animals? Or can we get out what we need by using 10?

He also explained that in his current work he needs to include making decisions ethically, indicating that ethics should be considered not only the outcome but also the process of making decisions. He said when he works collaboratively, "for the most part, in meetings, whenever we're making any kind of decisions, we're just making sure we are being ethical." James gave further examples of how simply caring out his work involves ethics. He first talked about expense reports.

> It could also mean, trying to think, could be anything. Filling out expense reports. If we have to travel for whatever reason, just, I guess, ethical situations, I guess, kind of arrive or present themselves in many different ways quite often.

James then also detailed the ethical relevance of reporting work time.

> Well, I mean, just like for our company, we report our time […] you also report how much time we spent on certain projects. So there's being ethical as far as reporting your time accurately, and also paying attention so that you can report it later. So from as soon as you set foot in the door […] Ethics kind of presents itself […] once you're in the door, are you working on the project that you are reporting? […] Are you, you know for me, doing experiments or doing any kind of measurements, you know, am I doing that correctly? Am I reporting all the results? Am I reporting the data? So I can, like I said, yeah, just pretty much everything I do, ethics is somewhat involved, I guess.

As a summary to his examples and how they demonstrated his experiences with ethical engineering, James defined ethical engineering practice in this way: "I would say, just doing your work, I guess, to the best of your ability. And being open, transparent, and honest with the way you do your work." His definition connects with the underlying idea that professional ethics begins with technical competence, as he emphasizes doing work to the best of his ability.

Cooper

During the interview, Cooper shared two experiences related to ethics she had while working as an engineer. The first experience she shared illustrates the centrality of following the right rules and procedures in ethical engineering that she experiences as an engineer working in the plant sites. She said, "every time you're doing a task that requires certain things, or certain equipment, or gowning, people follow that, even though it's just a piece of paper and a rule that's telling them that." She provided an example of proper gowning. In Cooper's words:

> In the plant sites that we work in […] gowning is very important, so *making sure that you protect the product and yourself* by wearing the right PPE, and also the right protection to protect the product as well. Personal protective equipment, or equipment that can also protect the product from a contaminant or something that a person might bring in. It's kind of an ethical decision for our entire plant site every day to do that right every time.

In this excerpt, Cooper highlighted the importance of proper gowning to prevent product contamination as well as personal safety. Although such a policy is established by the management, she said that it is on her to make sure that she is doing it the right way every time, since she is not watched 24/7. While she explained the gowning practice is now "almost second nature" for her since they need to follow the process multiple times a day, there is "an interdependent culture" in the plant site which ensures them to follow the right process. She said,

> When I'm going into the room usually someone else is in there too, one of the operations staff, maybe a quality person. Typically, it's operations staff that are more attuned to this practice, and they're known to speak up and help. If I start walking towards somewhere and I don't have my hairnet on, somebody will stop you and tell you, 'Make sure you catch back up' […] when I first started it wasn't natural for me to remember to do all these things, especially the different practices that there are, like putting your booties on over the fence, like making sure your gloves stay on until all of your gowning is off. Whatever the practice is, the gentle reminders from others are also helpful […]

But such required processes are not always followed well. Cooper shared an example in which she had to manage a situation when a contractor did not follow the required procedure. She started to say, "one of our operations staff let me know that he ran into a contractor out in the manufacturing floor with absolutely no over-gowning on. This is very much not okay in our area." She said eventually they cleaned the spaces where that person had gone by asking the person about the exact path he walked and how that happened. Later she evaluated the situation by saying,

> The person who spoke up to me and let me know that it had happened […] That person behaved ethically by notifying someone. They could have easily said nothing and just let

> it go under the rug. That would also be a concern, because we wouldn't have been able to take a preventative action for the future. That person consciously knew the policy, knew that this wasn't okay, and knew it was important to speak up […] the person who made the mistake, and wandered off, and took the time to explain how it had happened and where they went […] We bleach, mop, or clean the certain areas of the path that he had followed. He showed us that path […] It's an ethical decision by him to be honest, and tell us what had happened and how. And then, finally, following up and closing the loop is the final ethical decision that our team decided to take on. We needed to change the security on that door, and make sure it's actually locked in preventing this for the future. We could've just left it as is, but that would've also allowed this to happen again someday. That was maybe the third ethical decision that was made there, to clean the area behind him, lock the door, and really close the loop on protecting our quality of our building.

Cooper also shared another experience she had when she was working as a process engineer who qualifies new equipment. She said it is important to "show that it's capable of doing what we say it can do." By sharing her experience of qualifying a tumble bin, she said,

> So my responsibility on the front end of that was to write the testing that would show that this bin is capable of doing what we say it's gonna do, so it holds the right volume, it can do uniform blending, whatever that case might be for that specific instance […] say, 'Absolutely no falsification of data, what I see is what it is.' Those are general practices in the company as a whole.

Likewise, she emphasizes the importance of ensuring the equipment that she qualifies to perform well as it was supposed to do and not to falsify data during the process, especially because "we are using this equipment to make medicine at the end." Based on the conversation during the interview, later she summarized how she defines being ethical at work by saying,

> I think it's consciously and unconsciously making the decisions to follow your standard operating procedures, or SOPS. And if you notice someone else who's not following it, or something that doesn't seem to be adhering to a practice that you know, speaking up and doing something about it if you're capable. If you're not capable to make the change or to fix something, telling someone else. If you are capable, address things and make them better immediately.

Mustang

Throughout the interview, Mustang emphasized the importance of working with integrity. He expressly discussed the importance of data integrity and being honest. He explained that of "the seven deadly sins" in their company the ones that are the worst are the ones get people dismissed immediately which include lying and falsifying documentation. He said,

> So that's an automatic dismissal, which I think, in and of itself, says a lot about the company, and how they go about that, and how they treat that. The significance and seriousness that it means, when we put our initial and date next to it, that we're being

> accurate. We're being correct. We're being truthful, in what we do, as we make our medicines. I think from that perspective, that kind of bar is already out there. But, obviously, there are people that have not always adhered to that, or not always seen the bar in the same position, where I think it was.

He said what should be importantly considered during the documentation is being "able to tell the story and someone needs to be able to follow that line of thinking." He further explained this with an example of documenting the testing procedure and results:

> So, if there's a test that was done. Maybe it didn't come out the way that we wanted it to and we needed to redo it. Or, we needed to explain it some way. As long as we tell what happened, and what we did, I find out, that 9 times out of 10, whoever looks at that, is going to accept that. Because, we've told the story. I think where we get ourselves into trouble is where we don't tell the story and we leave it open for interpretation. Or, for someone else, five years later, down the road, to come in and try and decipher. They may or may not be able to do that, with just the data that would normally be there. So, that's where I think that we need to provide perhaps some additional information to help them understand.

This quote highlights that engineering ethics includes recognizing the obligations that engineers have to future engineers. These obligations include properly documenting their work for future reference.

Mustang also had a few years of experience of working in another industry, especially in procurement. During the interview, he shared an experience related to ethics he had as a technical buyer. Although the context of this example is outside of the health products industry and Mustang himself thinks this example is slightly away from a technical engineering role, we decided to introduce this example too, because this example aligns well with Mustang's general perception of ethics in engineering and can provide insights on non-technical aspects of chemical engineers' daily work. Actually, although Mustang said procurement is not necessarily a technical role, he said it is mostly engineers that work in that role. He said,

> I was working with circuit boards. So, we had a package that we were putting together, and trying to bid, and get leverage from our suppliers on quantity. So we felt if we gave them more business, that maybe we could get a lower price. And we had, at that time, currently, a 100 different circuit board designs that we were putting out. These were going to be several millions of dollars worth of contracts. And we went in, and we had one supplier, who came in, and was the low bidder on 98 of the boards that we sent out. So, out of the 100, they came in on 98 of them, they were the lowest bidder […] I can remember my boss, he was called in […] to make some significant changes, called in the president of this company, and will do, what I say was a bald-faced lie, and told him that every single board that he had bid on, we could get for a cheaper price. I'm sitting in there, with a colleague of mine, knowing that that was not the correct answer. That, in fact, that was not true.

Reflecting on this experience, Mustang said, “it came as a total shock.” He said, “as a result of that meeting, when we walked out, my colleague was actually in tears, because she said that we lied.” Later Mustang said because of this specific incident, he and his colleague resigned and took different positions. When asked what elements of this experience were related to ethics in engineering, Mustang answered,

> I think, as an engineer, we are very data-driven, that we work off of facts […] When we have that data, I think it’s inherent upon us to present the data in the light and context that it was taken. When we had the data, that we did the analysis, and said that here’s where the prices were on the boards, and there were 98 of them that they were the low person on, to say something other than that went against the data that we had. In my mind, like I said, there again, that was a lie. I had nothing that I could back that up with […] in this case, I had the data, and we went totally off script. Like I said, I couldn’t support it at that point […] Like I said, he went totally against what the data showed.

In summary, Mustang perceived this situation as a misrepresentation of data in order to hold a lead in negotiation, therefore the boss’ behavior was a breach of data integrity. Aligned with what he shared, Mustang later defined ethical engineering practice as,

> Taking that training, that we’ve had, assessing the situations, gaining the data, and not going with predetermined prejudices, or biases. Looking at the data that’s put before us and then making clear, concise, decisions. If we don’t know what all the answers are, to just to tell the story.

Carpathian

During the interview, Carpathian shared an experience he had while he was working on the simulation for a drug product during a stage before it even underwent clinical trials. He said,

> The work that we were doing […] seemed to indicate that a dose of suggested for clinical trials, one of the doses that was suggested was at a level that was at a similar risk of side effects as other doses, and yet at a very low [level] of efficacy […] It was an arm of a study that we felt would have little to no benefit to the study while having a similar risk to patients as other arms, which we then discussed with the clinical design team, and through discussions we were able to successfully remove that arm from the study, as suggesting that it would not have a high benefit to us while at the same time having similar risks to patients.

This excerpt details the concerns about whether an arm of a clinical trial should proceed and how this decision depends on the ratio between the potential benefit that can be obtained from the study and the expected risks to the patients that could be caused by the clinical trial. Carpathian thinks that if the expected risk is higher than the potential benefit, the clinical trial should not proceed; and based on such thought, Carpathian and his colleagues decided to remove that arm of the clinical trial after discussion. He said in suggesting the modification of the original study design, it is important to “use […] scientific rigor to convince others of those outcomes without doing the actual experiments and eliminate experiments.” Carpathian also clarified that, “all drugs carry this

risk, but once we know what the risk is, we evaluate it relative to its benefits." While he said, "if it's a drug that increases survivability of a cancer or increases a progression free rate, those risks are tolerated," he pointed out that this level of benefits was not the case in this scenario.

Throughout the interview, Carpathian continued to discuss the importance of considering benefit to the patients. Later he said,

> A lot of the designs and developments that I here do in my simulations will often indicate a high or low likelihood of drug performing properly, or performing as it were or not performing, and us just having reduced efficacy for example in a subset of patients, which when I see that, we will then perform animal trials in order to ascertain if that's an issue and then work towards resolving that issue through modified formulations […] you see something that indicates that there may not be as high of an efficacy as we would hope in a subset of a population. You do redevelopment verification. Eventually it will all end up with a formulation that will have the best possible performance across the broadest range of patients.

As he emphasized the goal of having the best possible performance across the broadest range of patients, another experience related to the issue that he shared was:

> I […] occasionally come across a drug that we're developing […] its performance would be limited to a subset of patients. So, I've had a case where since we were going to market it without a label limitation essentially […] I felt that we would need to verify that its performance would actually be sufficient across a certain subset of the population […] So I worked on developing a set of experiments to show that it would be an issue in a population subset through developing some animal trials. And then suggest formulation modifications that would improve that outcome, and we are actually right now working on a general formulation design that would mitigate those effects across that whole range of drugs that fit in a similar category.

Carpathian thinks limiting a drug to only a subpopulation of the patients "seems to me to be a little unfair," because he believes "whatever work we do should be geared towards improving the overall state of society as much as possible." He said unless they cannot figure out an alternative, they need to resolve the issue to expand the ability of the drug to benefit a greater number of people. He says, "to me that seems to be the more ethical use of resources."

Later in the interview, Carpathian defined ethical engineering practice as "practices that improve outcomes for others. Improve benefit on society or reduce risk to others," while pointing out the fact that engineers "don't operate in a vacuum."

Taz

Taz works with manufacturing operations and does engineering analyses for various sites within the organization. In his interview, Taz did not give many specific examples, but rather talked through some collective experiences to highlight some of his general perspectives on ethical engineering practice. The following summarizes his general narratives.

Throughout his interview, Taz indicated that, from his perspective, ethical engineering practice is primarily about proper compliance to internal rules and regulatory guidance. However, he also recognized that while following rules and regulations is generally straightforward, there can be times when there may be questions about how to follow both the rule and the ultimate intention behind the rule. He said,

> I've done work that certainly involves regulatory compliance, both from a quality point of view and an environmental point of view, also internal rules and regulations that we have to follow. And mostly I've been able to do that work without there being a big conflict between the two I'd say. There are times when things are put forward to you and you say well the rules say this, and we follow the rules, but you do sometimes push back and say well does the rule really mean this, and is there an interpretation that says […] can we meet the spirit of the rule.

In such situations Taz indicated that he may feel he needs to make decisions what actions to take and how to do so effectively. He detailed some things that may be included in making these decisions:

> There's different elements to it […] It's being honest with your assumptions, with your data, with your analysis, it is seeking to comply with what are design standards, or regulations are in place. From the technical side, I'd say that's what it entails. And you can get into the personal side, like making sure you give a proper attribution for ideas and concepts and work and those kinds of things as well […]

He went on to identify additional critical factors that may help with understanding and making decisions about ethical engineering practice and technical versus personal factors.

> Well some of that is imposed from the outside, and some of that is internal. You have regulations and requirements and design things, and those are sort of external things you're complying with. And then the more interpersonal things are just that, they're between you and another person, they're more internally driven.

Taz also included thoughts on how considerations about power, company influence, and the support for performing to ethical expectations might impact the decisions he might make.

> There have been times, I'd say it's not looking at say, violations of regulatory things, but internal situations where there are procedures or rules in house and you'll have […] I've had people in positions of authority... Occasionally, it's not happened a lot, a few times, say things are busy, things are hot, this is a project, do what needs to get done, even if it involves going around this requirement. And that's been a point of contention a few times. Not very often, but has happened.

Taz then explained what he considers in such times of contention.

> You wanna stay in compliance, you are also in the reality is you're gauging what's the power relationship between you and this individual, what recourse do you have, and is that hill worth dying on? And also what's the general environment of the company.

In his interview, Taz also discussed considerations for his own and others' reputation.

> Your reputation counts for a lot. And you work on that and it's very easy to screw up and have that tarnished and very hard to recover. So it's something that you try hard to live up to what you hope is a good reputation […] I think, again, it's the thing that I mentioned, and for me it's also reputation that goes with it. It's the idea that people trust you with the work that you do. That they know you're not fabricating things, that you're not […] they know that you are, as best as anybody can be, you're an honest broker with what you tell me and what you present to them.

As a summary to his experiences with ethical engineering practice over the years, Taz concluded,

> Well, I mean again, it comes down to […] You gonna have personal integrity, you gonna have an understanding of why you have rules and regulations, and we work in a very highly regulated environment. And what we do has significant consequences to people. Both to the company and to the patients. So you always have to be thinking about that stuff. And, again, it's rare that we're put in any kind of position where we really gonna be confronted with […] And I'm glad of that.

Angela

Angela is a chemical engineer working in an engineering management role. In her interview, Angela stated, "every day we have to make an ethical decision when it comes to making medical devices". She recognized that their industry is very patient-driven and talked about how she and her colleagues apply a focus on decisions about the patients to their work by asking questions. She provided examples of the patient-based questions that they may ask:

> We ask ourselves, 'Do we feel that there is a risk to the patient, such as you would not be comfortable putting this device in your mother, your child, your sister or your best friend?' And so I think that's really a benchmark for us to say, 'Yeah.' And if the answer is no, then we have to say, 'Okay, well what would we do to mitigate that situation?'

To further illustrate an emphasis on decision-making with the patient in mind, Angela also talked about her experiences in reviewing product quality. With this example, she provided a series of questions that she and her peers ask when receiving feedback from users of the products they develop.

> So, I think every time we've received that feedback we have to say, 'Is there an engineering change that we need to make? Do we have to inherently change the design?' What is our burden to educate these physicians or provide better education to help them with their implant techniques to be more successful? Are we in a situation where we feel that the product is no longer favorable and that risk to benefit analysis?

To stress the criticality of decision making in ethical engineering, Angela summarizes,

> We have to make the decision on whether or not this product is beneficial to the patient at the end of the day. That is, in my opinion the heart of ethics in engineering, is making

> sure that we're making good engineering decisions and making good engineering judgements on what's in the best interest for the patient.

Angela also described several more examples which she felt demonstrated additional dynamics in engineering ethics which related to managing people and their work performance. One of those examples she described as "beneficial" and "eye-opening". In this example, she and another manager had an employee who was not performing to expectations. In this event, the manager of the employee had a conversation with the employee through which they both discovered and accepted that the employee was not comfortable in her role and with being responsible for making decisions. However, they were able to find the employee a different role which was a much better fit and Angela related this example to ethics by further highlighting the importance of decision making in ethical engineering practice and making decisions for the best interest of all. She declared,

> I think as it relates to the discussion that we've had, the importance of being able to be confident in our decision and the burden that we put on making the best decisions to our patients. That person just wasn't comfortable in that situation. So, we found a role that better suited her.

Angela then provided a second example related to managing performance in which she had to have a conversation with another employee who was underperforming. In this example, after asking question and following up on performance expectations, it was determined that the employee was not suited for working with the company and continuing to employ them would ultimately have a negative impact on the product customers as well as the patients. Angela explained her responsibility as a manager was to terminate the employee. She explained the "In my part I felt that it was the right thing to do, not only of course from our business standpoint, but really for the employee." She further explained how being in a leadership role has ethical responsibilities and personnel issues such as these are relevant and do require ethical decision-making and practice.

> I think people look to leadership as being the example of how they should handle situations or really how the company handles situations, both from the standpoint of being fair and being challenged hearing the ideas of others, acting with urgency, acting in a patient's best interest. All of those for me personally are facets of what I believe to be a direct representation of the company and how I try to also conduct myself to be that example, and also to reflect my expectations of my team. So, I would not think it would be ethical if I believed that people should do XYZ things that I would not be willing to do by myself. That would not be how I would want to conduct myself.

When asked if she could describe an example of engineering practice that did not involve ethics, Angela thought through some possible examples but ultimately concluded that,

> At the end of the day, every action that we take is a reflection on ourselves as a person, and especially for myself I feel, in a position of leadership, people look to you to be that example of ethical behavior, so I don't know that I can say definitively something that I do is not based in ethics.

Discussion

Overview of descriptions of experiences

Based on the analysis, we reported descriptions of six chemical engineers' experiences related to engineering ethics. Although we focused on only chemical engineers who are working in the health products industry in this study, we could still find diverse experiences across different individuals which included experiences related to data integrity (Mustang) and experiences related to ethical leadership (Angela) among many others. Thus, one of the important findings of this study is that ethical issues are pervasive in many aspects of daily practice of chemical engineers. This highlights the importance of including a breadth of examples when providing ethics instruction to chemical engineering students. As an example, instructors might use James's story to explain that professional ethics begins with technical competence but extends beyond complying with laws and regulations. James's stories also highlight that ethical considerations include both the processes of decision making as well as the outcomes that result from those actions and decisions. Instructors also could then use Mustang's stories to explain and further demonstrate how engineers are responsible to future engineers and their work.

Thus, with this work we suggest that chemical engineering educators can utilize the presented descriptions of practicing chemical engineers' experiences of engineering ethics for developing ethics education case studies and other curricular tools. And while we encourage educators to also find additional creative ways of using the descriptions, here we highlight a way of utilizing these descriptions aligned with a *micro-insertion* approach.

Integrating the descriptions of experiences across chemical engineering curriculum via micro-insertion

The prevalence of ethical issues in various elements of chemical engineering practice aligns well with the micro-insertion approach suggested by Michael Davis [22]. Michael Davis introduced micro-insertion as a type of "pervasive method" of ethics teaching, which makes ethics components appear across the curriculum. He defined micro-insertion specifically as a technique that "introduces ethics (and related topics) into technical courses in small enough units not to push out technical material" [22, p. 717]. In his article, he provided an example of applying the micro-insertion technique to thermodynamics courses, which "engineers seem to think among the least hospitable to teaching ethics." [22, p. 723] He introduced a technical problem which involves enough context surrounding the required technical analysis based on which students can ponder over ethics factors together with other factors to make suggestions about the problem which account for the multiple factors.

While Davis provided a detailed guideline for inserting such an ethical component in a technical course, a good example of implementing such the micro-insertion approach throughout the curriculum was also suggested by Yau et al. [28]. In their paper, the authors introduced how they integrated an engineering ethics component into their 3-year chemical engineering diploma program in Singapore. They integrated engineering ethics modules with different themes across micro and macroethical issues into various courses in their chemical engineering program, including but not exclusively: introductory chemical engineering, environmental engineering, and

thermodynamics courses. Specifically, in the environmental engineering course, they implemented a group discussion on a case study about leakage of chemical waste in off-site location, and in the thermodynamics course, they required students to complete a reflective journal about nuclear energy.

Khraisheh [29] also advocates for improving chemical engineering ethics education by implementing the micro-insertion approach out of consideration of the challenges related to an already fully-packed chemical engineering curriculum. Additionally, while touting the advantages of the micro-insertion approach, Khraisheh [29] recognizes that, to be impactful, context-specific case studies will be especially necessary. For example, for students to have opportunities to reflect on ethical issues throughout the curriculum, there need to be various cases each of which fits well with the content of the course.

Since our study results provided six descriptions with various ethical issues, we expect that educators can utilize those in different moments throughout their curriculum. For example, Cooper's gowning example can be shared when students are attending laboratory sessions, to show how the requirements in their current lab sessions (e.g., wearing gown and goggles properly) can be related to their future workplace requirement. Also, Cooper and Mustang's data integrity examples can be introduced in the lab sessions where students need to write and submit experiment reports. As we briefly discussed, Byrne [7] suggested that cases may be more effective when students can relate them to the situations in the cases. Therefore, introducing these descriptions when students do similar activities is expected to be able to provide students with good opportunities to learn how the ethical practices they are learning will relate to their careers.

As Davis [22] suggested, instructors can take a "hit-and-run" [22, p. 724] approach with these descriptions, wherein instructors simply introduce the descriptions in proper times in the curriculum. However, if there is any extra time, or if instructors are motivated to go further, they can lead a deeper case discussion, to further engage students with the descriptions of practitioners' experiences. For example, instructors can use Cooper's example of the violation of gowning and have students discuss what they would do if they were Cooper or the contractor who violated the required procedure before sharing Cooper's response with them. After discussion, students can compare their ideas with Cooper's response. Also, instructors can use Carpathian's example of the target population decision to facilitate discussion about potential users of the health products with the concept of justice, which has been argued as an important principle of bioethics [30], in the courses related to the pharmaceutical process engineering.

While we mainly discussed the potential use of this study results in the context of the micro-insertion, instructors do not necessarily need to take the approach. Chemical engineering faculty members may also consider developing a stand-alone course (e.g., a simple 1-credit course) for students who are planning to work in the health products industry and introduce these descriptions as case-study materials. Also, the results of this work in collecting descriptions of practitioners' experiences may be used to develop other pedagogical tools like role-play scenarios, and experiential learning reflection prompts.

Limitations and future work

While this paper can add value to chemical engineering education literature as described, several limitations to this work does help identify further research opportunities. First, while we introduced detailed descriptions of experiences of six individuals which already showed meaningful variations, all chemical engineers we introduced in this paper are from the health products industry. Since chemical engineering graduates work at a variety of industries including oil and gas and food, we recognize that a different industry context could affect the types of ethical issue the engineers encounter. Further studies which explore different chemical engineering industries would be helpful to better understand the full breadth of chemical engineers' practice and the range of ethical issues they experience in their workplaces. Second, while we introduced how chemical engineering educators can potentially use the six descriptions in this paper, we have not yet implemented these ideas ourselves, so we do not know how effective such an educational approach will truly be. Further studies are needed and encouraged, especially the studies which investigate the effectiveness of pedagogy that utilizes the descriptions of experiences we introduced in this paper.

Conclusion

In this paper, we introduced six descriptions of experiences of engineering ethics in the health products industry which were constructed based on practicing chemical engineers' experiences. We identified that even within the six individuals' experiences, there were a range of ethical issues including rule compliance, testing procedures, and responsibly to leadership roles. Furthermore, we substantiated that ethics is pervasive in chemical engineers' daily practices. Therefore, we suggested chemical engineering educators consider taking a micro-insertion approach with the descriptions we introduced in this paper to improve ethics education for chemical engineering students. Since ethical issues are pervasive in professional practice, relevant ethics instruction should be pervasive in engineering education programs.

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