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So I'll go ahead and introduce ourselves I'm Peter Schwartz I'm director of the

Center for Bioethics I'm here to welcome you to the next week's treats talks are

a alright and we monthly or now actually

like three thirty minutes presentations

or shorter on a key topic that we research

the recorded and archived our archives currently down to which we are working

to correct default so I'm going to

choose Mary who's a professor of pediatrics and even more importantly a long time so we give me a topic I've

been begging for years now and now we get about distinguishing quality

thank you everyone and I am talking about Qi because as an ethicist it's my

most common curbside consult where I if

I'm talking to fellows or residents or postdocs about research behavioral

research for elf I'll say while doing this to my project they don't know whether I should or whether he did what

I do with it and so I thought well let's look at this these issues around July the ethical issues the overlaps and

distinctions between Qi and research and I want to give and so my talk is built

around a set of key questions how do I

distinguish Qi from research is the first question and that's practical question for researchers so

then as I started to dive into distinguishing here I realized it really

wasn't much of a distinction so I want to talk to talk about applying our

current and then talk about some

alternative or what I think are perhaps more appropriate so one is sort of quite

a practical approach to qi and research to address really let's sort of push the

issue and think about one of the underlying efforts to research but in a

minute we're into you a little case that just came up last month one of the

fellows I was working with approached me about a Qi project she's working with a new adolescent clinic in Kenya and

they're having a lot of difficulty getting their adolescent HIV patients on contraception and family planning it's a

huge issue because I attended pregnancy among young women with HIV so this

little is planning a Qi project which puts together theirs but it turns out

like globally there's a lot of interest in implementation approaches to adolescent family planning

like we know family planning works with contraception we can delay so the

question is really how be implemented so her colleagues in other countries in

other places globally really interested in their approach so she's planning on presenting the research journal so her

first question as well as this researchers so these are pieces of what

she did she was over there was texting me back it was super cool but they

started with a problem statement so poor uptake in family planning services HIV

patients atrophy center of excellence listen to health the something called

Graham where you look at all the different you should you make it like a

fish don't you take all the different areas where there may be barriers identify those barriers

Solutions and she used a plan do study act approach so they took one piece of

their fish implemented that piece and then we are looking to see are the

number of kids is the uptake of family planning higher so now I ask is this Qi

or is this research very fast what was the intervention I can't remember what

they did they did sort of like some like they're in so it's progressed along one of the interventions was educating

clinic staff and confidentiality and educating clinics in contraception and

another intervention was having the nurses an expert in contraception automatically meet with every kid which

we had certain age range so they had a series of interventions that they did as part of this I want to do they have a

question before us right yeah

maybe yeah so I'm going to say

so Canton people's and I think a really important observation so but so this

project actually is a really nice example of qi methodologies in in

contrast research methodologies are quite different and i just sort of threw

up the hierarchy of evidence where you start out with in vitro going animal studies case reports case controlled and

cohort studies controlled randomized controlled trials and then systematic

reviews and meta-analyses and these involve like systematic study they comparison groups involved sampling so

the methods that are typically used in research one thing is that these are a little bit different than

using Qi and so like thinking about this

distinction between you research and Hugh and I have to say our I'm unit

subjects office has done a great deal of work on this and they have this really nice tool on their website so for anyone

actually doing Hugh oriented work or comparative effectiveness research I would strongly recommend logging on to

our HS a website in looking at the toolkits that they provide also using

our HS o staff to run by questions about is this qi is this research but nor i

you HS know definitions or basic on federal definitions and they define

quality improvement as data collection or analysis for internal operating in

operation monitoring program improvement so in this case the key issue is internal and they sit said that the data

could be originally collected for other purposes so in a Qi project that we're talking about for adolescent

contraception they in a chart review and just looked at whether the young person

had contraception on their medication list and as a question on their charts

they also you can also use Qi data or written communication that's done

specifically for that purpose Qi can also be implementation and accepted

practice so the key piece of this is an

accepted practice so an intervention it's already been studied and you're looking at the actual implementation

part of it so you can alter the Houston accepted practice and collect data to

evaluate is attacked in the emphasize that is not designed to

contribute to generalizable knowledge so these this is our I you HS so

definition I mean it's a it's helpful when you're looking at your project that you can certify or is this research

[Laughter]

these comments that feels like it's really obvious that when you start

through what makes something not generalizable then then you know it's

sort of questions are underlying assumptions so I need this idea that this is done like this intention in a

specific clinic with a specific group of providers like you saw that detail but

you know one of the issues the adult

medicine increasing very specific to the

question their forms so these are lacy

cheeky and look like questions and we know from research on provider prompts

that if you put the prompt on to the form whether it be electronic or paper providers are more likely to ask so

their first one of their interventions was putting up more which is this sort of very generalizable

you know this idea of you know sort of the particulars are really important to

the end so this is the IU who so one of

their tools and their project really

focused on the learners as opposed to coming up with a generalizable approach

that could be used anywhere but the questions you know becomes in this particular case like using a few is

using UI methodology looking at the particulars and addressing the particular than a generalizable approach

is there Qi approach to prove a holistic contraception then sort of generalizable

to other mobile income context so the

intent would be to cite a generalizable knowledge versus improvement of a practice process services in the

institution design life we talked a little bit about it research frequently involved in Paris randomization and

comparison groups but they're people who do that he wrote resurgent like along the spectrum so you have qualitative work that really

doesn't involve randomization keyline in

contrast it also creates cycles but may involve embarrassing pension

organization I mean if we think about like the Qi and comparative

effectiveness research projects that engender the storm of interest in the

ethics around qi and consent they were surgical checklists where they used a

clustered randomized design where they had centers doing searchable checklists

and centers not doing surgical gem checklist so they used a sophisticated study design had vandalization and had

comparison groups that it was like essentially a quality improvement issue just using a surgical checklist helped

with post surgical outcomes at their centers in their system so population

frequently in research should be using a subset of the broader population if I

was generalizable tall adolescents you're gonna use a subset of adolescents and provide sensory statistical and

sampling justification where's Qi you'll get most or all of the young people getting the treatment

program processes so Catherine looked at the last 50 patients that they served in

their clinic to see whether they had had whatever intervention that you know

whether they had been asked about sex and whether they had any out taken

contraception we can think about effect so for research the intent is usually

not to directly affect the practice where you're at but it might affect it as opposed to directly informing

practices and policies from a benefit perspective participants may or may not receive

direct benefits from research so we think about you know hypertension trials where depending on which group you're

randomized to you might or might not see it but this contrasted Children's

Oncology Group where almost every trial look over 80% and on a clinical trial so

kids they use this sort of research as integrated entry 4qi participants and practices usually

directly benefit dissemination for research is expected where you would

expect people to present and publish their q is not assumed and what it is

presented they want to suggest that that fit models strategies assessment tools benchmarks things like that so we have

so this is our tool and these are sort of thinking about like what are the differences so you press this qi i found

this really helpful some of my projects are more Qi oriented where we take we're

looking at adolescent sex education we can evaluated effective program

implemented in community and look at my

communication with parents so you know there are things that are more Qi oriented things that are more research

oriented and this is a tool for investigators and top if you feel like yours is somewhere in between you can

call up our IRB talk to one of the member vhss staff and have people there

that have some expertise in determining UI versus research and regulatory oversight you might use this use of the

tool for the ancient oppressors help me do work beyond yourself one would be if any of the lines checks off on research

then you're the research world certainly that last time of the first one right it's like you're planning publication

you're planning presentation you plan it's not that you know overall all of

the happy consider one line to our research vendor in research this is a second question about a brainy

one of the lines is your question sort of how strong the side that's where the question like let's say presentation to

making the case you get read this publication is soon that's not the main reason why you're doing that enough the true

factors in the main reason I'm doing that enough to keep it on the QI side is

that key to that case you're saying it being qi is that all they were planning percent that wasn't the reason there

when I do it as a distinct philosophically plan presentation

publication yeah so I'm in it I'm going to take the tent for two slides or three

slides because I'm going to address it because I think it is important and so I

mean in in this location at this time so

the intent is one the other thing is how to use these checklists you know and you're like if you get one do you move

over so there's actually a paper on a checklist that looks very similar to our checklist and they put for it if you're

anything in the research column you should be considered research I personally am Not sure I agree with

that because I think that there are really good Qi projects that do use randomization like a surgical checklist

like imagine you have to get as you're implementing a checklist you would get

individual patient consent for every single checklist you know they did have

a comparison use randomization and they used an alternative trial is online with cluster randomization so you know so I

would say that there are well-designed Qi projects that use techniques that we

typically think about as research techniques on the dissemination I think

it's really an old view that if you disseminated it's automatically research because I think if you look to the right

like you know this idea of having effective models and strategies is really important it may not be like the

particulars of you know what the Qi project is doing so for instance

mustard and you know what are they doing in what interventions that they choose but the model of taking the individuals

in the clinic getting representation from all the professionals involved in this too embarrassing to medical

personnel and then it's so it'd be the publication would be focused on this

approach and disseminating this approach to increasing family planning update which doesn't make it not you I you know

so and I think you can assume publication because it's a really important issue any maternal morbidity

is one of the biggest killers of young girls internationally so this is in contraception is one of the most

effective ways of reducing maternal morbidity so so she is like the plan to

publish it is actually quite reasonable

so here she wants to publish it and ask to colleagues whether Qi has to have

ethics in any or IRB approval and so

this is the Qi associated colleague one says different qi results are a publishable quality and she's been asked

for approvals for secondary data analysis after the project is completed and colleague to said absolutely not

who's right low and middle-income countries

you asking it call me my not appalling -

who is right there are two correct answers to this yeah let's take a vote let's call it one right call it - right

are neither right so IRB an ethics

committee oversight so for publication and funding so journals and fun thing I

put often require but my recent experience is 100% of the journals that I have put my work in every fired

documentation an IRB oversight or a determination by the IRB that oversight

is not required so they want me to have submitted my project to the IRB in Reis

and so the funders also require documentation of IRB oversight so I have

you know I have a grant where the funding hasn't yet been released yet because we're working through IRB

approval and that money will come once they get IRB approval so it is the

shoe a practical issue here so our health human subjects office doesn't

they clog an application their non human subjects research in that application

they'll determine whether IRB oversight is or is not required and then that will

generate an iron her IRB documentation inexpensive it and

you would do this beforehand so this is something that our IRB does and I have done it and incredibly hopeful because

it maybe as an investigator really consider like one of the issues what's the intent when the publication pieces

whatever you know so it's still like sort of work through like is this um is

this project in the right pocket the other thing I would say because we're talking about my example was from an

international project regulations or countries specific in international

researchers need to check on both things

like that would be just as a pragmatic thing you know so intense so at tabled

intent so intent is really important it does matter for ethics committee an IRB

approval is the intent to approve processes in your system or is the

intent to produce generalizable knowledge so does Katherine does the

business Qi project want to just improve uptake a family planning at the Medici

Center for Excellence in Adolescent Health or do they want to produce a

reproducible approach that you can pick up and plop down anywhere so intent is

really important so the other intent question was intended for those attempt to publish naked research

No yeah no this is the thing is like no it doesn't anymore like instead we have

whole journals of Qi you know does it intend to publish alone who doesn't make

it research intent to produce generalizable knowledge makes it research your intent about your main

purpose of doing it is it focused on your system and improving your system versus improving your improving like as

as something that is like going to be more like you can pull it out of your system and put it anywhere in you know

there's a range here and there's huge amounts of overlap so this is one of my concerns about generalizability because

Qi can be generalized if the contents aren't correct it's like the quality of work right qualitative work isn't

generalizable in a sense that's generally done for the homogeneous population when you're trying to

understand the range and depth of in that population but you can take it and

apply it to other similar populations so

miss intent is your intent to improve your system and one of the questions I ask is with you and one of the questions

that was asked of the person that had done the hue I project you know it was

like will you do the project even if you couldn't get it was not publishable and like her answer was absolutely yes this

needs to get done it's really primarily focused if it won't have achieved its

goal if it never gets always represented anywhere look at it'll just maybe it's

like splitting hairs too much but the funny thing is for me my intent is that it strikes me that to some extent it is

because I was not in the same research worldview all right but like to some extent any type of research in a way

would be quality improvement just if I'm trying to do surgery like a type of surgery that's because I want to improve

the outcome for this and mutual silly to me there's almost what makes a quality improvement is that

it feels like is systems so what a

learning healthcare system research the

other thing is there's not like buckets of researching buckets of Qi there's sort of a spectrum of things so you know

where some things are clearly just Qi and some things are purely research

establish best practices establish keeping on learning healthcare system

that would still be a very clinical patient yeah research we had a case a

couple of years ago where there was not

looking there is an approach to a particular problem where it's the surgery and kids they do open surgery

and infants and aggregates because they're so tiny and if your kids thank you by surgery and there's this like

medium sized yes where it's not clear which is better and it sort of depends

on you see a bit more comfortable with because there was no standard for them and so they proposed a comparative

effectiveness thing because there's no standard can you randomize the kids to one or the other the support trial is in

neonatology is everybody familiar with a support trial the comparative effectiveness trial and I try and try to

remember the numbers but like so it turns out that premature newborns definitely need

oxygen supplemental oxygen but they don't need too much oxygen if they don't

get enough oxygen and affects brain development but they had too much oxygen there like toxicities that are oxygen

and so within the nursery there was sort of an eight-point range that they would keep the kids oxygenation and some

people captive more towards the upper end of the range some people kept it more towards the lower end of the range it was really personal preference of the

clinician and style and there weren't data there so they randomized the kids within the acceptable best practices

range to the upper end versus the lower end and in this trial was not as

comparative effectiveness trial you know but I didn't get engendered it turns out

like looking retrospectively did the cadet consent forms give full disclosure

really interesting that was make sort of a storm so I think that you know you're

hitting this idea of comparative effectiveness research like what happens in it it's a nice example of something

that sits at the junction of research and Qi so going backwards so retroactive

approval I mean you just can't do it it's not ethical like I did this research that you know I

did this thing that I called Qi that it really it was research and now I want you to approve it so the person that

said the colleague that said no can't be done is in some sense correct however

there are situations where you do secondary data analyses of projects

utilizing data collected from a Qi project and this may in fact represent

human subjects research and you can at that point slide you know

lies it as a secondary data again you get to this issue of an intent if the secondary analysis isn't the primary

intent of the program but you've looked at these data that were collected as

part of your program evaluations part of the Qi project and so like we could ask really interesting hypotheses of these

data then you could go back and apply a secondary data analysis so I think it's again it comes to this idea of intent is

it honesty of researchers so so the mean

is summarized and see if you agree my summary what you're saying as long as

your primary reason for doing the project is to actually improve quality

even if the back of mine you realized some possibility maybe even your plan as

long as your primary reason for doing that cynically not and you're good for

so you know I have to say on it like so I'm saying yes it's still quality

improvement that is you're thinking about regulatory oversight then that is the type of project that I would ask ask

myself one question is if I couldn't get approval to submit this from publication

what I still do it which is a matter of privacy you're interested second thing

that I would do is it would strongly recommend talking because maybe you get

to these things that are on the margin it's really there's a lot of stuff on the margin you really need their input

for regulatory perspective so ask yourself one question ask carve the same question so here are my

ethics concerns with what we're doing now so it's all nothing like so there

are really high oversight burdens of research which provide an

incentive to redesign Qi hiding comparative effectiveness research such

that they're not classified as reset search so you get less rigorous sampling design and analysis and I would have to

say very ethics perspective the one of the first ethics questions we have to

ask about research you shouldn't be doing this research at all with individuals and if we are can we do it

in a way that is the most scientifically rigorous so that the data that we get it

is able to be that we can use to improve healthcare so I think that really this

oversight what you end up with this isn't all or nothing the situation is particularly problematic in areas like

Pediatrics or prison research populations because these groups were not considered when they did the new HR

recommendations so a lot of things in the adult world would be considered exempt population is nice so

you end up with really high over state burdens around consent and stuff like that protections that are really important if

it's like a vacation trial of potentially toxic medication perhaps less important if you're talking about a

cluster randomization of a surgical checklist there's a need to know

oversight for qi it's just considered part of practice so it's not like our HSN law is there if they're charged as

human subjects research we don't have an equivalent July office each individual system has like things

around July and they have like some people that Qi committees some people required

some organizations require rqi be submitted there's no consistency to it and a lot of Qi is just sort of done so

you have minimal to no oversight and there may be some patience and there's

an ability so I think the oh nothing thing really doesn't serve patients it

doesn't serve investigators so I really have concerns with our current oversight of Qi around this um the distinction

between Qi and research is really really fuzzy so we the psyche of generalizability so I would put forth

like clinical trials have highly selective populations treated in controlled conditions that we will never

be able to reckon to repeat in real

life so is this actually generalizable

you know whereas Qi is conducted in real world settings with like the chaos of

clinics and does that actually make it more generalizable you know if asked

like who are you generalizable to so I would say the first Qi project that we

started with around uptake contraceptives planning like that's like

the specific actions that they do are not generalizable to individual patients at another place but the system in their

approach is generalizable to other adolescent clinics in sub-Saharan Africa

so taking this approach is generalizable although the actual choices has specific

activities that they came up with as part of their Qi project may not be generalizable or very sort of particular

to the location and context so I you know generalizable at what level is it generalizable through rigor so hue I can

have randomization comparison groups use advanced analytic methods people doing

hue I have the same desire to reduce error improve validity is people doing research and many researchers

very few I work and research or to work right at the at the where that you come

together in then there's the issues around risks and burdens to patients

like a lot of um it wasn't on a mine thing that a lot of groups you look at like what's the risk a more than a

patient like research that as hot you soon high risk to patients high burden

as opposed to Qi having like gettable to no burden to patients but I you know are

different than what they would get in as part of routine clinical care so I'm going to argue that risks in terms of

patients is also not a way to differentiate Qi and research so

arbitrary distinction so like funding plan for publication and in all mental

researchers these are the things that are proposed as ways to differentiate Qi research but this sort of arbitrary and

don't have or don't have to do with patient well-being you know so so I

think that there's like some of the pieces are arbitrary and then it's a

torn fit for today's ethical means like our current model really grew out of the National Commission for the protection

of human subjects reports of the 1970s and they were responding to gross

negligence and abuses of individuals involved in research and they make a

sharp distinction between research and practice in or highly focused on patient

protection and patient right so the cornerstone of that is autonomy and like

focusing on patient can send a patient understanding of the research process and not just giving them information

that they understand that information and in some ways you know what we're

applying this model autonomy trumps all because you would never you know so you

know because in consent is easily sort of this cornerstone to it so that's our current model of oversight missing

though is what I would consider an equal ethical imperative for adjusting health

care system so we need a health care system where people have access where

there's quality where there's affordability the other ethical piece that's really missing and no offense

either that like the protection the National Commission report was primarily like making this and it's very much like

we the physicians and system and you the patient so like the page their

obligations from the provider to the patient but also for the patient and provider their obligation to the

provider there are these by directional obligations so then just work in there

because it's just a very patriarchal focus on protection approach so where

does it leave us so over say not the IRB then who and I'll just say I honestly

don't have the right answer to that and it's way beyond this top going to talk

about in my last little bit of time is another ethical framework to start

thinking about so economy beneficence and justice and I think looking at

learning healthcare systems for Kela is where we need to be from the ethics so because the goal of the learning

healthcare system is a just and equitable health care system in a learning healthcare system is this idea

that health care systems have an obligation to continuously improve and

that it's acceptable and essential to integrate search and quality improvement approaches in the practice the purpose

of a learning healthcare system is to generate that's why the best evidence for the collaborative choices of each

patient provider dyad to drive the process of discovery as a natural

outgrowth of patient care and not something separate from patient care in to ensure innovation such that we can

improve quality safety and value in our healthcare system so this is this idea this sort of overarching goal learning

healthcare system and there has seven proposed fundamental obligations to

learning healthcare system and these actually fit well for qi so first is respective races dignity of

patients so this is the autonomy thing but the idea is that this is one of seven it doesn't so the first thing they

asked is does a Qi activity limit the choices of patients or the value of

their choices and if not then then that

puts it in a niche state if not and if so puts it in different pockets because not all Qi activities are attached to a

significant autonomy interest in actually deferring could be a moral

failure to care for the patient so I'm going to go to the surgical checklist which were phenomenally effective so

that way they would not have been able to do this type of research we actually

order to improve the care of our patients so respecting the rights and

dignity is first looking at like are we limiting their choices and not limiting

their choices and you know sort of how can we move forward respecting clinical

judgment is also certainty or limited

evidence then the likelihood that under certain clinician judgment would advance patient interest is lessened so there

may be some wiggle room in this and I think this is a key pieces there's one shopping mall providing

optimal care each patient so does the expected net clinical benefit Qi activity higher than non-participation

this is going to be specific to a Qi projects particulars avoiding imposing

on clinical risks and burdens so we have an obligation to great protections to

reduce risks and very similar analysis of nominal access but putting it into

the context of a clinical system applied to our patient the dressing unjust in

qualities this is where we have to system-level ethical obligations and we're Qi because Qi functions at the

level of a system so you know our current regulations focus on their

subject selection just distribution researcher escaper benefit but I would

argue that we actually have an affirmative obligation for Qi to reduce

or eliminate inequities in evidence they don't offer clinical decision making and inequities and healthcare delivery

so we have market inequities and this is something that our system is really

adequately obligated to address so we rapidly obligated to target disparities

and clinical outcomes conducting Qi to continuously improve the quality of

clinical care in healthcare systems so we have like basically but this seven

fundamental ethical obligations as saying as we actually as professionals are morally obligated to perform Qi to

integrate learning into our healthcare system and finally is this by

directionality so there's an obligation of patients to contribute to the common purpose so just as systems and

professionals have obligations to patients that an obligation to contribute to a participating Qi and

it's this norm a common purpose one philosophy in here so Rawls

principle of the common good is sort of adapted to this normal common purpose

that we want to create a height we all have a common purpose professional systems and patience to create a

healthcare system that has high quality that's high quality efficient effective affordable and this assumes obligations

of reciprocity I receive a tentative society I should which is the quote is

service to others is the so away you

know when I'm going to propose is that the seven that we when we're thinking about the ethics of Qi we sort of move

away from autonomy beneficence justice and really think about these balances

here you know because they also come an obligation to reduce to respect my

rights it's something that and that's really sort of this is something and we have

this obligation to do what's best so position actually has six obligations

and the patient's just have one obligation but they're sort of checks and balances to the point yes yeah

and they have made it number seven we have to meet one through six or

you get to number seven and the other piece isn't there's more and more individuals that are like yourself so

Nancy Cass and Sproat was looking at alternative methods for comparative effectiveness research and Qi and they

did a public deliberation where people are educated about the topic for a couple days and then they're asked to

weigh in and consider like in a series of questions when they were asked about

is like what types of consent approaches for comparative effectiveness research

would be acceptable to them one of them was just being told that comparative

effectiveness research was going on in the clinic on an individual interaction

with their provider but just you know here's our approach HIPAA here's our approach to this and we have these

really doing comparative effectiveness studies going on so that you know about them

another approach was opt-out so like you can we have these studies you have an

individual discussion you can opt out if you want but if you don't no doubt we're going to have you go forward and a part

of the study the third wasn't often labor you would go through more of a traditional

incentive process and you know not surprising you know people favor often

over opt out over general but people favoring it was like 70 it was

like 80% no one was at 70% favored adopt in like 65 favorite off doubts who

really similar to this opt-in versus out and 40% with that person in certain

context it would be acceptable to just do a general like this is what's going on which is you know really intimate

these data are really interesting these data from individuals who you know

presumably they've been sort of you know educated about what's involved in comparative research and pragmatic

trials and it was limited to this thing that it was sizing her the University

Medical Group and so so but I think here

your point is well-taken but I mean it's it's also a piece that's been missing in

research and healthcare systems in general trying to publicize so you

create having the rigors of research with the oversight to drive that be the ideal system is that right I think

there's so right now there's no oversight at you I so I'd have to say that you know playing into what I'm

proposing is more that we rethink oversight in terms of qi and include

these principles in the oversight and these principles would allow more flexibility and research oversight I

mean so that's that would be my sort of my proposal or it but it's just I don't

know that I mean Hugh is so particular in systems are so particular in and of themselves are not sure and that sort of

a separate talk is like how would you even do like what are the pragmatic issues in

and who IO person I'd be interested to hear what Regan Street does for it it's

taking on individual projects yeah

yeah so this is in that would be sort of what's best practices for Qi

right now is the organization takes over the oversight and make sure that

patients dignity rights are respected make sure that make sure you know so so

i think you know as opposed to like if it's something like if that would fall into the research it's very be out like

sort of federally mandated and international thank you all