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Intermittent Catheter Reimbursement in the United States: The Experience of Nine Stakeholders Through the Lens of Actor-Network Theory

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Abstract

A narrow interpretation of “medical necessity” can result in poorer health as well as a more restricted life for people with disabilities. We examined the impact of US policy on reimbursement of intermittent catheters (ICs) on the lives of people with neurogenic bladder (NB) who require catheters to urinate. We conducted in-depth, longitudinal interviews with nine stakeholders. Actor-Network Theory was used to describe interactions among human agents, IC products, and policies in the reimbursement arena. Restrictions on the type and quantities of ICs reimbursed emerged as the most potent inhibitor to health and wellbeing among consumers with NB. IC suppliers, due to the large number of other stakeholders with whom they interact in the reimbursement process, emerged as strong enablers of preferred IC use among people with NB. Lack of an impartial central clearinghouse on IC products and coverage impeded consumers’ ability to make informed decisions.

Keywords

actor-network theory, interpretative phenomenological analysis, disability-competent care, intermittent urinary catheter, neurogenic bladder, reimbursement, spina bifida, spinal cord injury

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Intermittent Catheter Reimbursement in the United States: The Experience of Nine Stakeholders Through the Lens of Actor-Network Theory

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A narrow interpretation of "medical necessity" can result in poorer health as well as a more restricted life for people with disabilities. We examined the impact of US policy on reimbursement of intermittent catheters (ICs) on the lives of people with neurogenic bladder (NB) who require catheters to urinate. We conducted in-depth, longitudinal interviews with nine stakeholders. Actor-Network Theory was used to describe interactions among human agents, IC products, and policies in the reimbursement arena. Restrictions on the type and quantities of ICs reimbursed emerged as the most potent inhibitor to health and wellbeing among consumers with NB. IC suppliers, due to the large number of other stakeholders with whom they interact in the reimbursement process, emerged as strong enablers of preferred IC use among people with NB. Lack of an impartial central clearinghouse on IC products and coverage impeded consumers' ability to make informed decisions.

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Introduction

The individual (sometimes termed, "medical") model of disability construes disability as lying within the individual and reflecting the consequence of physiological limitation whereas the social model of disability frames the locus of disability in the failure of society to provide appropriate services and assure that the needs of people with disabilities are taken into account in its institutions (Oliver, 1990). In US health reimbursement, the concept of *medical necessity* drives which products and services will be reimbursed (Palsbo & Kailes, 2006) but is not grounded in criteria endorsed at the broad societal (national) level (Bergthold, 1995). Reimbursement policies that interpret medical necessity inhibit the societal participation of people with disabilities and decrease well-being (Palsbo & Kailes, 2006). The purpose of this study is to explore how the process of reimbursing urological supplies in the US, specifically,

urinary catheters, shapes the urinary self-management of people with neurogenic bladder (NB) and influences their health and life choices.

NB occurs when neurological damage or disease disrupts the normal urination process. People with NB urinate using urinary catheters, hollow, tubular devices inserted into the bladder through the urethra or a surgically-created stoma. Even when medical management is optimal, people with NB are at increased risk of life-threatening urinary tract infections (UTI) and renal complications (Dorsher & McIntosh, 2012; Manack et al., 2011). Up until the last quarter of the 20th century, renal failure and sepsis, consequences of impaired bladder emptying, were among the most common causes of morbidity and mortality in people with NB (Ginsberg, 2013). At least some degree of NB is common (over 80% prevalence) among people with spinal injury or disease (SCI/D; Taweel & Seyam, 2015). NB and related voiding pathology also occurs in virtually all individuals with spina bifida (SB; De Jong, Chrzan, Klijn, & Dik, 2008).

In the 1960's, a study involving newly injured persons with SCI showed that the technique of intermittent catheterization, inserting a catheter several times a day to remove urine, was associated with a lower rate of UTI than using an indwelling, continuously draining catheter (Guttmann & Frankel, 1966). Later, in the 1970's, the use of clean, intermittent self-catheterization (CIC) in those with SB (Lapides, Diokno, Silber, & Lowe, 2002) had a similar effect on UTI. In the almost 50 years since Lapides first introduced CIC, it remains the bladder-emptying method of choice for people with NB (Lucas, 2019). Catheter technology has evolved however, and along with it the need for prescribers and payers to decide which features are medically necessary for which individuals (Lamin & Newman, 2016), effectively shaping the options of people with NB relative to bladder management and how they structure their lives around it.

In an earlier study, we identified the range of urinary symptoms experienced by people with SCI and SB who use ICs (Tractenberg, Garver, Ljungberg, Schladen, & Groah, 2017). We observed that individuals manage urinary symptoms, in keeping with clinical consensus (Lukacz et al., 2011), by increasing fluid intake, leading to increased catheterizations and, as a consequence start to deplete their catheter supply. In the US, ICs are a specific class of urological product, provided monthly, in capped quantities, through public and private health insurance programs. Since emptying one's bladder is not optional, fear of running out of ICs led to behavior that put individuals at risk for redoubled infection -- reuse of inadequately disinfected ICs (Avery et al., 2018) -- or decreased social participation, particularly among women who have run out of ICs suitable for use in public toileting facilities.

The picture of the IC that emerges from the literature is one of a technology that has evolved to address the health of people with NB holistically, supporting both physiological and psychosocial wellbeing. However, the contemporary US health care system, through its reimbursement policies, conceives the fit of an individual IC product to the person who relies on it more narrowly, typically (though not always) endorsing the minimally appropriate system that safely supports the strictly physiological function of urination. There is no central information clearinghouse that individuals with NB can consult to understand which insurers offer which IC options, under what circumstances and at what cost. This lack of clarity makes it extremely difficult for people to take charge of their bladder health and navigate their way to an IC solution that is optimizes their personal needs.

Our interest in conducting this study was to better understand the patterns of resourcing that people with NB use to get their ICs and the barriers and facilitators they encounter. We wanted to get high-level insight into how resourcing took place, who was involved, and how strategies modulated in response to changing circumstances. A focus of our group's research over the past six years (see Support) has been to identity the priorities of people with NB with respect to urinary outcomes, criteria they identify as important to their quality of life in

managing urinary function versus the strictly medical priorities that may be reflected by the health care system. We have personally observed how health care policy, which IC technologies are paid for and by whom, influences individuals' decision making around how they manage their bladders which, in turn, is reflected in their decision making relative to life goals and how they will participate in society.

The interests of authors on this manuscript vary, but coalesce in our deep concern for optimizing the wellbeing of and opportunities available to people with NB. MMS, is a technology researcher with a specific interest in how people use technology to enhance their function, particularly in the context of disability. She has functioned as the qualitative methods lead for our group. AKR is a rehabilitation researcher who has been extensively involved in field research related to bladder management among people with NB who experience a wide variety of levels of voiding impairment. TMcM is an individual with SCI well-versed in the science of neurological impairment. He has worked with us extensively since 2014 in conducting and analyzing interviews and focus groups involving people with NB. AB and HC are disability policy experts who have, likewise, been members of our patient-centered outcomes research team since its inception. HC, additionally, is an individual who himself has an SCI. SLG is a physician SCI researcher who served as the director of the grant (see Support) under the auspices of which this study took place.

Methods

Overall Approach: Use of an Actor-Network Theory Framework

We used an Actor-Network Theory (ANT) conceptual framework (Latour, 2005) to explore the interplay of persons, organizations, policies, and technologies that make up the IC reimbursement ecosystem in the US. ANT is distinguished by its treatment of human and non-human actors - people, things, and abstractions - as all exerting influence, creating push and pull, in the networks in which they act. We adapted the phases of ANT analysis described by Carroll and colleagues (Carroll, Richardson, & Whelan, 2012) to the specific, healthcare reimbursement context of our study. See Table 1.

Table 1
Actor-Network Theory (ANT) Phases

ANT Phase	Description
I. Identify the stakeholders	Identify the human (people, capable of volitional acts) and non-human (ex. rules, technologies, money) actants who influence or are influenced by one another in catheter reimbursement.
II. Investigate the stakeholders	Examine the experiences and perspectives of human stakeholders through interviews and review of the documents they provide.
III. Identify stakeholder interactions	Trace interactions among stakeholders to explore how they influence one another.
IV. Construct an actor-network model	Visualize such aspects of the network as convergence and distribution.
V. Identify inhibitors and enablers	Determine who/what enables and inhibits actions in the network.
VI. Examine irreversibility	Determine to what degree it would be difficult to make a change.

Adapted from the analytic paradigm (McBride, 2000) as summarized by Carroll, 2012, p. 60.

Research Questions

Aligned with the ANT perspective, the following research questions guided our inquiry:

1. What does the US intermittent catheter (IC) reimbursement network look like?
2. What are the inhibitors and enablers in the network ecosystem that impact bladder management practices, health, and quality of life among people with neurogenic bladder (NB)?

ANT Phase I: Identify the Stakeholders

Recruitment and Participants

We purposively recruited consumers[1] with NB and varying types of health insurance plans, public and private, to explore their experience of IC reimbursement. We conducted in-depth, semi-structured interviews using a guide (available at https://1drv.ms/b/s!AnAG82yv9Ycphc8A-32B8S4fF5zTxg?e=wZCy1L) adapted from an instrument previously developed by our research group for use in focus groups involving people with NB who used ICs for bladder management (Tractenberg et al., 2017). We chose the semi-structured interview format to make sure we asked all of our pre-determined questions while at the same time keeping the process sufficiently open-ended to capture the breadth of people's IC reimbursement experience we had glimpsed in our prior work with people with NB.

Our initial consumer participants identified other stakeholders in the reimbursement process whose interactions strongly impacted their access to catheters. We subsequently recruited a physician, a representative of a catheter supplier/distributor, a catheter manufacturer representative and a disability advocate, to triangulate information and sharpen the picture of catheter reimbursement. A total of nine individuals participated in interviews[2] (see Table 2). Six were consumers: four with NB and SCI and two caregivers (parents) of minors with NB and SB. Two participants brought a dual perspective to their interviews. One individual with SCI and NB worked as a nurse practitioner with patients with NB. The catheter supplier product and service specialist was, in addition, the mother of a child SB and NB. See Table 2.

Table 2
Stakeholder Profiles (Pseudonyms)

ID	Sex	Role(s)	Catheter Use Profile		Catheter Coverage	
			Type	Rx Amount	Primary	Secondary
Amy	F	Consumer, SCI	Closed	6/day	Private Commercial	None
Beatrice	F	Consumer, SCI	Straight (M & F)	90/ month	Medicare (Public, federally administered)	Private Commercial
Chuck	M	Consumer, SCI; Nurse Practitioner	Straight	4/day	VHA (Veterans Health Administration	TRICARE (US Military Health System)
Don	M	Consumer, SCI	Hydrophilic	8/day	VHA	None

[1] We believe the term "consumer" is a better fit than "patient" in describing our participants with NB/caregivers as the focus is on reimbursement of a commodity that is consumed and replenished, the IC.
[2] The study was approved and supervised by the MedStar Health Institutional Review Board, Washington, DC USA.

ID	Sex	Role(s)	Catheter Use Profile		Catheter Coverage	
			Type	**Rx Amount**	**Primary**	**Secondary**
Ellen	F	Mother of male child with SB	Hydrophilic & Closed (50:50)	6/day	Private Commercial	Medicaid (Public, administered by individual states)
Fran	F	Mother of male teen with SB; Supplier	Hydrophilic	5/day	Private Commercial	Medicaid
Gillian	F	SCI Specialist (Physician)				
Hank	M	Manufacturer				
Iris	F	Disability Advocate				

ANT Phase II: Investigate Stakeholders and Identify Their Interactions

Data

Given that our participants were geographically dispersed around the US, all interviews were conducted by phone. We used a professional service to record all calls; the same service also provided smooth verbatim transcripts of each interview. The person conducting an interview was also the individual who verified its transcript. Interview data were captured at two time points. The first round of semi-structured interviews, 19.0 to 66.8 minutes in length (mean = 43.6), were with all nine participants. After completing our preliminary analysis, we re-engaged seven of the nine participants in follow-up interviews. These follow-up interviews, 24.5 and 91.1 minutes (mean = 46.4) in length, took place from 9.4 to 13.8 months after initial interviews. The purpose of re-engaging participants was to share and verify (member-check) our initial understanding of IC reimbursement, and gage, longitudinally, how individuals' experiences or perspectives might have changed since our initial conversations. We followed up with the remaining two individuals whom we did not formally re-interview, via e-mail.

Transcripts were uploaded to a cloud-based qualitative data analysis application, Dedoose (SocioCultural Research Consultants, 2018), to facilitate collaborative analysis. Explanation of Benefits statements shared by consumers and catheter policy-focused documents provided by the disability advocate were also managed centrally using Dedoose. Our general impression was that all participants we spoke with were extremely forthcoming. The phone versus face-to-face communication medium for discussing a topic as personal as urinary catheterization may have enhanced candor.

Analysis

We followed an Interpretative Phenomenological Analytic (Smith, Flowers, & Larkin, 2009) approach in identifying themes in and across interviews. We chose to use an interpretative phenomenological analytic (IPA; Smith et al., 2009) approach to making sense of our data for two reasons. First, a network as conceived within ANT theory, is a phenomenon in continual flux that we set out to understand through our participants' interactions with it. Second, IPA provides a thorough, stepwise process for evaluating each case on its own merits before intermingling themes with those coming from a different case.

For each individual participant, we began by reading and rereading the transcripts (re-listening to audio recordings for tone if there was a question of emotional charge or irony), creating initial memos and assigning open codes, to borrow terminology from grounded theory (Strauss & Corbin, 1998) to identify emerging themes. Disagreements about interpretation were resolved by discussion and consensus. We subsequently noted connections across themes within an individual interview and repeated the process for each successive interview.

We began to identify links across participants as soon as the initial analysis of the first two interviews was complete, exploring whether emerging phenomena inhibited or enabled the appropriate acquisition and use of ICs by people with NB. We iterated this process, expanding and refining our framing of cross-cutting themes until each interview was considered in light of the others. We sketched out a preliminary model of actor-network relationships and went back to our stakeholders for the second round of interviews to clarify and expand on questionable points and receive feedback on the model of IC reimbursement developed.

Results

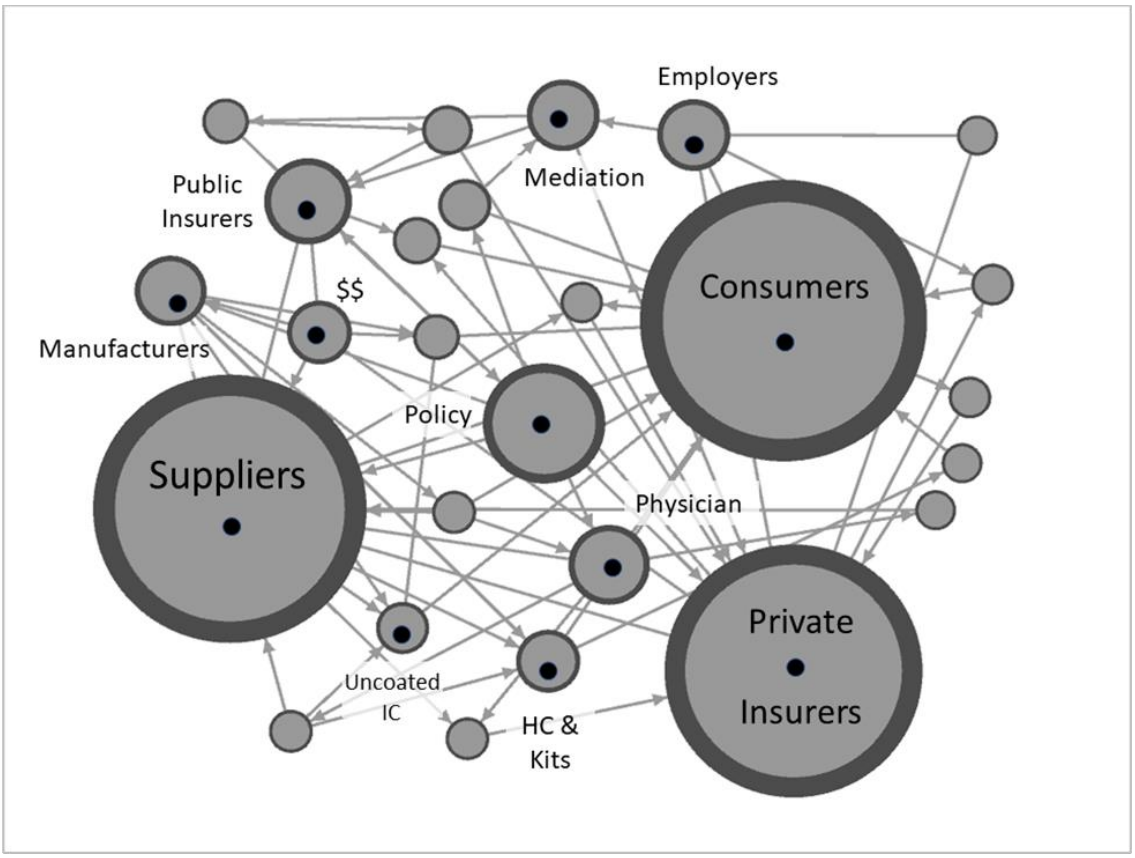
RQ1. What does the US intermittent catheter (IC) reimbursement network look like?

ANT Phase III: Construct an Actor-Network Model

The actor-network model (Figure 1) provides a picture of the interrelationship of people and components in the overall process of catheter reimbursement via experiences of the stakeholders we interviewed. Labeled actor-nodes had an interaction count of five or greater with other actor-nodes. These interactions and more peripheral ones are described below. The supplier interacted with the largest number of other actors in network, followed by the consumer and the private insurer.

Figure 1

US Intermittent Catheter Actor Network. Connectivity Among Human and Non-Human Actors. Labeled nodes have a degree of 5 or greater (range, 2-14), showing suppliers, consumers, and private insurers as the most "connected." Constructed using Gephi v. 0.92 (Bastian, Heymann, & Jacomy, 2009).



RQ2. What are the inhibitors and enablers in the network ecosystem that impact bladder management practices, health, and quality of life among people with neurogenic bladder (NB)?

ANT Phase IV: Source of Inhibitors and Enablers

The catheter reimbursement network described by stakeholders contained both inhibitors and enablers of people's optimum acquisition of ICs. Perceived narrow reimbursement rules and procedural burden inhibited people with NB to get the ICs they felt most appropriate to their bodies and lifestyles. This burden interfered with their ability to receive sufficient quantities to assure their ability to empty their bladders, whatever contingency life might bring. The catheter supplier emerged as the reimbursement network enabler, the actor in the right position to get the consumer the most appropriate IC, in a timely fashion, at a satisfactory price.

Few Reimbursement Codes, Many IC Varieties

CMS sets the rules that drive catheter acquisition: which consumers (based on medical criteria) can receive reimbursement for type of catheters, what cost, and quantities. Three categories of intermittent catheters are recognized -- straight, coudé (curved), and sterile kit ("closed") -- and all products are required to meet the criteria of, one of these three types to be reimbursed (see Table 3).

Table 3. Intermittent Catheter Codes, Descriptions and Reimbursement Limits

CMS Code	Description	Usual Maximum Quota	Notes
A4351	Straight Catheter	200/month	Includes one individual packet of lubricant per catheter. Least expensive IC
A4351	Hydrophilic (coated) Catheter	200/month	Pre-lubricated with touch-free, "gripper" insertion mechanism. Reimbursed as a straight IC, but typically exceeds the reimbursable amount. Some payers, such as VA, will cover if medical necessity, such as recurrent UTI, documented by a physician
A4352[3]	Coudé (curved) Catheter	200/month	Includes one individual packet of lubricant per catheter. A more expensive IC, requires demonstration of medical necessity.
A4353	Sterile Intermittent Catheter Kit (aka Closed Catheter)	200/month	Most expensive IC. Comes with gloves and other equipment to perform sterile IC. Requires physician documentation of two UTI within the past year meeting stringent quantitative criteria. Exceptions include being a resident of a nursing home, immunosuppressed, a pregnant woman with SCI, or having radiologically verified vesico-ureteral reflux.

Source: Noridian Health Care Solutions, LLC. Local Coverage Determination (LCD): Urological Supplies (L33803) https://med.noridianmedicare.com/documents/2230703/7218263/Urological+Supplies+LCD/3aeb7caa-2773-4c83-acdc-758d245fd643. Updated 10/9/2020, retrieved 10/23/2020.

[3] None of our consumers had used coudé catheters, nor did they figure prominently in the experiences related by our catheter industry informants or disability advocate. They are listed here for completeness, but don't figure in the article itself, as a result.

CMS pays one price for any product within the specified code regardless of quality within product codes. Accordingly, consumers whose insurance, for instance, Medicare, only pays on the CMS fee schedule are constrained to pick a catheter at or under the CMS price point. Increasing consumer options was identified as a concern by Iris, the disability advocate: "Looking at the Medicare space as a whole, and looking at the health reform space as a whole, we are constantly pushing for variety of products in plans."

Contrary to the impression created by reimbursement codes, ICs are a technology under continual evolution, manufactured in a variety of materials, sizes, incorporating features to reduce risk of infection during cathing as well as to enhance user comfort, convenience, and the overall esthetics of catheters. Fran, the catheter supplier and mother of a teen with SB, described the surprised reaction she encounters at product expos. "When somebody comes to my table and they see that there are 30 different kinds of catheters, they're like, "I didn't even know there were all of those out there!"

Within each of the categories CMS uses for IC classification and reimbursement (see Table 3), manufacturers work to attract consumers to their products by focusing on the subjective experience of cathing people with NB encounter in everyday life, as Fran's description of her typical interaction with potential clients at product expos suggests. Manufacturers compete to differentiate their IC products by offering a wide range of designs and price points. Areas of focus include enhancing the individual's personal and social comfort with the IC through discrete and attractive packaging, promoting convenience in preparing the IC for insertion, and addressing the comfort and efficiency of cathing by taking into account such individual differences as limited hand function, body mass, and agility. Disposability, both immediately after use or at a later time as may be more appropriate in certain context such as visiting friends, is a further product differentiator focused on designs to augment the wellbeing of the whole person.

Private Insurance and Coverage Uncertainty

Private payers also use the three-tiered coding system established by CMS for the three categories of catheters. However, they retain autonomy to determine the terms of the coverage they offer, particularly in plans they negotiate with large employers who, in turn, offer these products as part of their employee benefits package. The business relationship established between the insurer and the employer around the contract is an enabling condition. The creates an opportunity for discretionary action if the employer chooses to intervene on the employee's behalf with the private insurer. Ellen related how she enlisted her employer's greater leverage with the payer for her son with SB. "When we ran into issues getting coverage, I reached out to the head of Human Resources and had her call the insurance company, and got it straightened out."

Fran, the supplier, however, explained that she could never tell a client with private insurance what coverage was available for a given catheter product until her office "ran their insurance." Two consumers with the same private payer but different employers are likely to have different coverage under the different plans sold to their different employers. Amy, a woman with SCI, described her difficulty in calculating her actual out-of-pocket expense for catheters when she switched to a new, nominally less expensive plan offered by her company.

> *My catheters were covered last year, but I changed to a different plan. It's a high deductible plan, cheaper each month, [but my catheters] are not covered. March was the first time that that claim [e.g., for catheters] was submitted under the new plan. So, on my Explanation of Benefits, where you see like a balance of $2,000 for catheters, I have yet to receive anything [a bill] from*

> *[supplier.] We'll see at the end of the year if it actually was cheaper, depending on out-of-pocket [expenses]. (Amy)*

The Explanation of Benefits (EOB) Amy references is the usual way US health insurers, both public and private, communicate to their policy holders about health products and services they have agreed or declined to reimburse. The EOB is retrospective; the service or product provider will typically submit a claim for reimbursement and the insurer will agree or decline to pay. If the insurer declines, the consumer is responsible for making the payment personally. The provider is expected to follow up with a bill to the consumer. What services and products consumers can expect to be covered by insurance and what their own out-of-pocket responsibility will be varies based on the terms of the specific plan elected. Individuals know broadly what their insurance will and will not pay for when they sign up for coverage. However, specific determinations are made when a claim is received. Appeal is possible and negative determinations can be reversed. The onus of appeal is on the consumer. Table 4 shows the components of a typical EOB provided to policy holders.

Table 4
Typical Explanation of Benefits Components

Component	Description
Patient details	Identifies the beneficiary, the person who received (or was denied) the insurance benefit
Medical services	Services (and products) received by the beneficiary and from whom, that is, services for which a claim was filed and processed
Amount billed	Cost of the services for which a claim was file
Discounts	Any money the beneficiary may have saved by accessing care or medical products from within the individual plan's network of providers, that is, providers with whom the plan has a special contract
Amount paid	The portion of the amount billed that the insurer paid
Amount not covered	The portion of the amount billed that the insurer did not pay
Other payments that may have been made	Some expenses not covered by insurance may be reimbursed to individuals through special, tax-preferential accounts (*Health Savings Accounts and Other Tax-Favored Health Plans*, 2020) they have established such as a health reimbursement account (HRA) or flexible spending account (FSA).
Amount outstanding	Any outstanding amount the beneficiary is responsible for paying
Terms and definitions	A glossary of the terms and definitions included in the EOB, as well as instructions for how beneficiaries can appeal a claim, if necessary
Specific details	More specific details about the cost of the services/products that the beneficiary received

Catheters Over-the-Counter

Coverage uncertainty impeded one's ability to plan but being able to purchase basic, uncoated, single-use, straight catheters over-the-counter (OTC) at certain retail outlets enabled consumers, at a minimum, to assure they always had a backup cathing plan. The question of which jurisdictions permitted sale of ICs without a prescription was equivocal. Consumers with SCI (adults) uniformly reported on the widespread reliance and availability of uncoated basic ICs as proof against failing to receive their regular, payer-reimbursed supply, of whatever type. Amy described her successful and unsuccessful efforts to get a stop-gap supply of straight catheters when there was a delay in receiving the closed catheter systems she regularly used.

> *You have to cath! Right? I have gone to a local [well-known retail pharmacy] that has a pretty good medical supply, and they have had catheters behind the counter. And they told me, "No, you need a prescription for this." Then, I go to the regular medical supply store and they're like, "Oh, yeah. What size do you need? (Amy)*

"You have to cath" identifies the central problem created by ambiguous policy governing direct-to-consumer sale of minimal, basic ICs. Missing even a day of cathing is health threatening. Amy's resourcefulness got her what she needed, but at a high cost relative to life disruption. The medical supply store she refers to is 45 minutes to an hour from her home and open 9-5 in contrast to the extended hours her neighborhood retail pharmacy provides for shopper convenience. Amy had to take leave from work to get to the medical supply store during business hours. She also had to arrange special transportation. Like many people with SCI, Amy does not drive. These efforts were absolutely necessary, however, to make sure Amy had a supply of ICs to get her through until her regular shipment arrived.

Hydrophilic Catheters

Basic uncoated catheters, available OTC, do not meet the needs of all people with NB. *Hydrophilic* catheters (HCs) are a more recently developed (and typically more expensive) product that has a slick coating and inserts touch-free with a gripper. These characteristics may provide a sanitary advantage over uncoated catheters to which the consumer (optionally) applies a lubricant. An increasing number of studies report a lower incidence of UTI in people using hydrophilic versus uncoated catheters (Clark et al., 2016; Rognoni & Tarricone, 2017; Truzzi, Teich, & Pepe, 2018; Watanabe et al., 2017; Welk, Isaranuwatchai, Krassioukov, Husted Torp, & Elterman, 2018). The more expensive-to-produce HC is coded the same, and reimbursed the same, as the less expensive uncoated straight IC, resulting in an impediment to access (See Table 3). Payers, outside of Medicare, may optionally cover the higher cost of HCs. However, this demonstration of need is based not on preventing, but on addressing a problem of recurrent UTI. Don, a veteran with SCI who wanted to take advantage of the health benefits associated with HCs, described the difficulty he had in persuading the Veterans Health Administration (VHA – colloquially, simply VA) of the legitimacy of his goal.

> *You keep trying to figure out what the statement is that they need to hear for you to get the type of prescription that you need. I'm telling the VA I want hydrophilic, and they're saying, "You don't."* -- *that saying you WANT something, isn't enough. You want something because of its benefit. So, for me to get the hydrophilic, because it wasn't a standard issue, I had to explain that I was getting bladder infections that were exacerbated, if that's the right word. [pause] Irritation from a non-hydrophilic catheter. (Don)*

VA is a national, self-insured health service provider and has a reputation for liberality in extending benefits to veterans. Don's experience demonstrates that despite its liberal stance, VA wanted to hear that the hydrophilic catheter was needed to remediate injury that purportedly caused UTI. That the literature suggests a preventive benefit was not deemed adequate reason for the prescription of an HC. Our disability advocate, Iris, expressed frustration over the lag in access to products this perspective creates in the US, that is not suffered by people with NB in other countries.

> *[Hydrophilic,] that's an ongoing issue, right? I mean, it's supposedly a new technology that's been around for what? 10 years at least! And these problems aren't the same in the European space, but in the US space, there have been various companies -- manufacturers that have requested an additional component for hydrophilic catheters. (Iris)*

Manufacturers argue that HCs are a class of products different from uncoated straight ICs (Centers for Medicare and Medicaid Services, 2014). However, CMS has not, as of this writing, recognized an essential difference between coated and uncoated products. As a result, the expense of a coated product is only supported when the more basic, uncoated product, results in demonstrable harm (UTI).

"Closed," Sterile Catheter Kits

CMS addresses the issue of UTI in its criteria for reimbursement of a sterile (commonly termed, "closed" or "all in one") catheter kit. The way the system is designed, the consumer or caregiver never touches the catheter during insertion and, after cathing, the entire unit – catheter, bag, insertion supplies and urine - can be discarded. Closed catheters are the most expensive type of IC. The bar is correspondingly high for closed catheter reimbursement requiring an individual to have two, physician-documented UTI, meeting highly specific, defining criteria (see Table 3), within the period of a year. Withholding an infection reducing IC until a person with NB, already vulnerable to UTI (DeJong et al., 2013; Dicianno & Wilson, 2010), suffers two severe infections impedes that individual's ability to prevent UTI. Iris, disability advocate, pointed out the dissonance between policy that repeatedly exposes people with NB to needing courses of antibiotics to fight UTI and the general population healthcare perspective on limiting antibiotic use.

> *It's not safe healthcare policy to put vulnerable individuals in the face of having to deal with more UTIs! We're trying to limit exposure to unnecessary medicine; if you have to take antibiotics enough times, you become resistant. It can be fatal if antibiotics no longer work and you can end up in a hospital with more severe medical conditions. (Iris)*

In the US, the general population policy trend toward greater support for preventive practices, such as the antibiotic stewardship those designed to mitigate the danger of antibiotic resistance that so concerns Iris, does have a parallel in policies applied to people with chronic conditions such as NB.

In the US, disease prevention policies, such as the promotion of antibiotic stewardship to which Iris alludes, do not explicitly recognize the risks accompanying reliance on urinary catheters for voiding. The Antibiotics Aware program promulgated by the US Centers for Disease Control and Prevention (CDC) focuses on treatment of infection once acquired and does not explicitly consider infection routes such as IC (CDC, 2019). Notably, in its guidelines for prevention of catheter-associated UTI, the CDC affirms that there is some evidence to support the role of HC in infection prevention (Gould et al., 2009).

Catheters as Enablers of Community Participation

Without a closed system, women with NB can face cleanliness challenges cathing when away from home. Fran shared her female clients' concern about public restrooms.

> *Men can urinate into a urinal. Women have to go into the stall. It doesn't matter if they washed their hands before they got onto the toilet, they have touched everything in the place. So by giving them closed bags it – even if they have to go into a stall -- it just eliminates a lot of the germs. (Fran)*

Apart from sanitation, toilet accessibility was another source of impediment. Amy described the life disruption she experienced when she ran out of closed catheters.

> *So, where I usually can cath from my chair with the bag, with these catheters that I get from the medical supply store, I have to transfer to the toilet and cath into the toilet --which at home is fine, but sometimes out in public, it's not feasible. So I do plan. Ok, if I'm going to go somewhere, can I access the bathroom because of this straight cath? Otherwise, with the closed system, if I can get into a private space with a closed door, then I can go ahead and do what I need to do. (Amy)*

The closed catheter was also identified as enabling a young child's developing competence in self-cathing. Ellen noted, "For my son, especially teaching him to self-cath, there's one closed system that he can use easily, and we would go through A LOT to make sure he gets the system that he's independent with."

Drawing on her experience with client product requests, Fran described a scenario of catheter provision fit to the life needs of an individual.

> *A spinal injury person who plays Quad Rugby for example, when they're at home, they actually want a straight catheter, no bag, so that they can urinate into their adjusted bathroom, that's been modified for them. When they are not in that ONE bathroom in the entire world, they want a catheter that they don't have to touch, that they can insert with one hand, and so they want a [brand name] compact set because it's nice and soft and it comes with a bag, and they can take care of their needs all by themselves, without anybody else. But when they're playing Quad Rugby, or possibly even just every day when they are in between cathing, they want a condom cath[4] on and a little bag on their thigh to leak into, so that they can catch the dribble so that their pants, that their wheelchair, and ultimately the floor, isn't being covered in urine. (Fran)*

The experiences described above show the range of concerns that people with NB have with respect to how they cath. The theme that distills from them all is the social importance of urinary management. It is a hallmark of the transition to adulthood as Ellen's deep concern for her young son's ability to self-manage demonstrates. Concerns about how urination will be managed shapes decision making about how and the degree to which one will participate in adult public life as Amy and Fran describe.

Not Having Enough Catheters

Payers' rules allocate catheters to consumers on a monthly basis and providers are subject to audit (and denial of payment) if violations are found. CMS limits ICs to 200 per month. According to Iris, Medicaid, in some states, provides even fewer. She noted, "We've

[4] A different type of catheter entirely, not intermittent

actually been active in working at the state level in pushing the 200 limit or at least making it a 200 limit to match the Medicare requirement at the state level."

The IC cap was an impediment addressed by consumer planning; all consumers had contingency plans to address delayed shipments, lost or damaged products, or accelerated catheter "burn" rates. Chuck, a Veteran with SCI and a nurse practitioner working with people with NB, confided that he has an emergency supply of catheters courtesy of an initial (undetected) double shipment.

> *I had gotten a double supply at one point. So, I've been able to continue with that cushion for a long time. I probably have a good couple of months supply. That cushion helps because, once you miss one delivery, you're getting into down to the quick, and we try to avoid that. (Chuck)*

Amy and Don experienced that being active in athletics was a common reason for using catheters at a higher than planned rate. Amy described the impact of swimming on her usual catheter consumption of six per day and her strategy for compensating.

> *When I'm swimming a lot, I have to cath more. So sometimes when I swim for two hours, I have to cath three times within that period. When I'm swimming four or five days a week, I run through a lot more catheters than I usually would. So then sometimes I will try to go longer between cathing: instead of four hours, five hours. Then maybe I have to run to the medical supply store to cover the next two or three days. (Amy)*

Notably, Don had negotiated an exception to the 200/month cap with VA; his prescription provided him eight per day, approximately 240/month. In the case of Beatrice, who was in the habit of supplementing her 90/month IC prescription with OTC catheters, a natural disaster threatened her catheter security. She told of a stress-filled five days trapped in her apartment with a dwindling supply of IC.

> *During Hurricane Sandy, for some reason, I was having -, probably from stress- just so much trouble using the short catheters! I was going through like dozens. I was in the bathroom with a flashlight [trying to see to cath]. I went through quite a few of them, just because I just couldn't, couldn't get it in! (Beatrice)*

Our informants demonstrate that fluctuations in life happen to people with NB just as they do in the general population. Choosing to increase participation in a sport, as Amy related, or being forced to cope with a natural emergency, as Beatrice described, both resulted in an unforeseen uptick in their rate of IC utilization. Certain medications may be prescribed PRN, use as needed. This concept does not extend to ICs, though experience shows that consumption is not static.

The Catheter Supplier as Network Enabler

The IC reimbursement network diagram (Figure 1) shows a cluster of activity inputs and outputs (14) placing the supplier at the center of the key transactions of product selection, payment negotiation, documentation, and fulfillment that take place across the network to accomplish the end result of getting catheters into the hands of consumers. In the VA system, fulfillment is centralized and the veteran/consumer rarely interacts with the supplier(s) with whom the VA contracts. On the contrary, in the case of our consumers with private or Medicare

insurance where the supplier is a highly visible, all reported highly positive relationships with their catheter suppliers. In Amy's case, she declined to leave her long-time supplier when she switched insurance even though she was told the supplier would be out-of-network and her cost for catheters undetermined. Amy explained her trust and loyalty to her supplier.

> *I have been with [supplier name] for years now. They're really great and I have a great relationship with them. The care coordinator that I work with told me that what I see on my EOB [under her new policy] will not be what will be billed. [But now] that amount of $2,000 on my EOB, it does concern me! [But I was also concerned, if I left my provider] that I wouldn't be able to get the catheters that I need and that I REALLY like to use -- and have that convenience of them being shipped to my house each month. So I'm just kind of going with it, because I do like the product and the service. (Amy)*

Our stakeholders identified responsiveness, product knowledge, timeliness, supply security, and ease of transaction, as being suppliers' key enabler characteristics. These traits also emerge from the perspective of the physician, Gillian, on the consumer-supplier bond.

> *It's very important to them [people with NB], that they've got a good system set up, and that they don't want to do anything to mess it up. If the distributor is, yes, responsive and gets them their catheters -- whether it's right or not-- in a timely fashion, and they never run out, and there's never a problem and it's easy, that patient's gonna stick with them because they DON'T want to get stuck without a catheter. (Gillian)*

The importance of product knowledge, as Gillian implied, an IC is most appropriate for a given individual, is perceived differently by those on the providing side (manufacturer, supplier) and those on the receiving side (consumers). Hank, the manufacturing stakeholder, valued suppliers' ability, by virtue of their position between product and consumer, to get new improved products into the market and in use. From his perspective, product knowledge was an important differentiator among suppliers. He provided a retail merchandise analogy.

> *We spend a lot of time [in product education] at the provider [supplier] level. Let's say you're going to go shopping and you have to decide whether you go to Target, Kmart, or another store. They all really are going to have fundamentally the same products, right? So then how do they differentiate themselves? They can offer to give you a better product, they can offer you a bigger selection, they can offer you samples so that you can try different things. (Hank)*

The consumer perspective on the value of the supplier's ability to bring product diversity, particularly the value of sampling, was more reserved. Ellen, particularly, had not experienced her supplier's understanding of product range and knowledge for product appropriateness for a developing child with SB.

> *I don't know if they [suppliers] are as attuned to subtle differences, which different closed systems are easier for a seven-year-old boy to use than others. It's more like, okay, there's a bunch of different things. Figure out which one is going to work best. (Ellen)*

Consonant with the physician's observation of a relatively low threshold for catheter satisfaction, Beatrice affirmed her confidence in her supplier but at the same time described her lack of interest in supplier's efforts to expose/interest her to new technologies.

> *I'm not a big catheter explorer, so I tend to stick with what I've been using for years. I know there're a lot of options out there now. [My supplier is] very open, "Hey, if you need any other kind of catheters, we can get those for you." They really work on behalf of the patient, such as myself. I've used one or two that have been sent to me as free samples from [supplier], but I have specific catheters that I use and stick with them. (Beatrice)*

On the other hand, Ellen told of attending product expos and Amy was an avid follower of manufacturer's product updates. She discovered, for example, that her ICs contained DEHP, a plasticizer with teratogenic properties, and she changed to a different product.

Beyond product selection, the supplier removed most burden from the consumer, managing everything from claims paperwork to getting catheters to the doorstep.

> *When we switched to a new insurance company, there was some leg work involved making sure that the new insurance company had everything that they needed. Our supplier, for the most part, took care of that. I have to say that they've been great about shipping times. Last week, I placed an order on Wednesday, and the box was here on Friday. Then in August, we were at the beach and it was the week that [my child] needed his supply, so they just changed the delivery destination to the place where we were! (Ellen)*

Finally, consumer out-of-pocket cost minimization emerged among the supplier practices consumers most appreciated. In the case of Amy, who elected to stay with her supplier, with uncertainty how it would affect catheter cost, her out-of-pocket expense ended up being zero. Over the more than 12 months that elapsed between her initial and follow-up interview, Amy continued to receive her preferred catheters and no bill from her supplier. Amy's EOB showed that the supplier is being reimbursed 80% of what the insurer agreed to pay the supplier, with the consumer responsible for the remaining 20%, for which the supplier, month after month, declined to bill. The supplier explained the business approach to catheter fulfillment that, ideally, addresses consumer catheter preference while minimizing their financial burden.

> *I rarely have any patients who are really paying anything for their catheters. For all commercial insurance, we send the catheters to the person, but we only bill the primary commercial insurance carrier, and then we don't charge the co-pay. [However], if your insurance is paying a dollar, and it cost us a dollar fifty to buy that catheter, we can't send it to you for a dollar. So, we may say, "Look if you can make up the difference in the cost of the catheter and the shipping, we are good. We might also say, "Would you be open to us sending you some other samples?" Most of the time, people are open to saying, "Oh, I'm open to samples." (Fran)*

Discussion

Five inhibitors and four enablers emerged from our stakeholders' experience of the catheter reimbursement network. They are discussed below, touching on their amenability to change.

Inhibitor1. Paucity of reimbursement codes, failure to differentiate HCs from uncoated ICs

As our disability advocate indicated, manufacturers have petitioned CMS multiple times to expand IC coding to create differential coding for HCs. Expert testimony presented reiterated the UTI reduction literature already cited using HCs. In one particular petition (Centers for Medicare and Medicaid Services, 2014) "work-around coding" has already been adopted by "many state Medicaid and private insurance agencies" (p. 23). CMS denied this petition, stating that the current codes were adequate, and the codes remain unchanged. Those with NB whose access to catheters depend on reimbursement falling within the CMS payment schedule that fail to establish a higher rate for HCs effectively inhibits access to a demonstrably safer product. Further, there is a large amount of evidence showing the cost-effectiveness of HCs in the health systems of such countries as Brazil (Truzzi et al., 2018), Canada (Welk et al., 2018), Italy (Rognoni & Tarricone, 2017), and Japan (Watanabe et al., 2017) due to associated reduction in UTI burden. We could find no similar study in the US system and no data on the number of individuals who would switch to HCs if reimbursement coding expanded. Worth mentioning is that one third (two out of six) of our consumers preferred using basic uncoated IC. Though this sample is very small, it suggests that not every person with NB would opt for HCs if reimbursement were liberalized.

Inhibitor 2. Opacity of private insurance

This topic was touched on very briefly but dramatically in the case of Amy who had to select an insurance plan without full information on the actual cost of her ICs. Lack of transparency of final, health service cost is a by-product of private, commercial negotiations among the parties to private insurance. It touches all insured health services, not just ICs, and does not seem amenable to change in the near future.

Inhibitor 3. Need to document recurring UTI to be eligible for hydrophilic catheters and closed catheters

The webpage presenting the US Surgeon General's *Priorities for Health and the Economy* (US Surgeon General, 2018) declares that, "It is widely accepted among public health and medical experts that it is more cost effective to invest in preventive measures that foster health and well-being rather than treating the manifestations of poor health." (para. 2) The need to experience two UTI to gain access to technology that prevents UTI is a policy in stark contrast to the Surgeon General's declaration. A diagnosis of NB should be adequate to secure reimbursement of lower risk ICs, both HCs and closed catheters.

The reimbursement code wording, "sterile" versus "closed," ignores how the technology functions not just to help individuals empty their bladders (a physiological function), but to help them, particularly women, move freely and participate in a world (social function). Two prior studies of ICs similarly identified lack of accessible (and acceptable) bathrooms and, for women, positioning to cath, to be the most prevalent problems reported (Bolinger & Engberg, 2013; Wilde, Brasch, & Zhang, 2011).

The CMS Medicare-Medicaid Coordination Office disseminates a Disability-Competent-Care (DCC) Self-Assessment Tool (Resources for Integrated Care, 2017) to help health plans and systems evaluate their implementation of the DCC model. DCC recognizes the whole person, responding to an individual's "physical and clinical needs while considering his or her emotion, social, intellectual, and spiritual needs" (p. 3). In the spirit of DCC, the catheter is not just a urological device allowing a person with NB to empty his/her bladder, it is technology that facilitates access to life activity on par with those enjoyed by people who void without catheters. Focusing eligibility for reimbursement solely on UTI prevention neglects the similarly important psychosocial function of closed ICs. CMS includes the DCC tool on their website suggesting the potential ability to use the DCC to expand closed system reimbursement.

Inhibitor 4. 200 catheter per month cap

Payer rules relative to the flow of catheters, restrict shipments to one per month and cap standard allotments to 200 catheters per month, threaten catheter security for consumers. Our consumers addressed this problem through conservation and leverage of OTC ICs. No explanation was found in federal records as to the rationale for capping ICs at the specific level of 200 per month when CMS eliminated the requirement to reuse ICs in 2008. Our stakeholder experiences suggest the current cap of 200 ICs is too low and should be changed, or that an explicit provision to establish a "catheter security cushion" should be established. Given the exceptions made in the private and VA systems, an increased number may be feasible.

Inhibitor 5. Lack of discernment among consumers relative to catheters

When a consumer, as was Don's experience, recognizes there is a problem with a catheter, it is likely to get addressed. If, on the other hand, a consumer is using a suboptimal catheter that is not generating problems at the threshold of awareness, there is no mechanism to trigger shifting over to better technology. Manufacturers and suppliers have the information that consumers need and some seek out, but there is no neutral and objective mechanism currently providing a clearinghouse. Disability advocates are perhaps best positioned to help consumers find and evaluate catheter information.

Enabler 1. Negotiability of private insurance plans between insurers and corporate purchasers

The employer is potentially a powerful ally to a consumer/employee in receiving desired IC reimbursement by virtue of the employer's client relationship with the private insurer. The potential benefit may depend on the value the employer places on the individual employee, and the employer's willingness to advocate. Appealing to one's employer in a dispute with insurance is a strategy that employees with NB should, however, be aware. Due to protected health information[5] and concerns about potential discrimination at work[6] consumers may understandably want to keep their personal medical needs private.

Enabler 2. IC variety

[5] Health Insurance Portability and Accountability Act of 1996. HIPAA gives consumers rights over their own health information. https://www.hhs.gov/hipaa/for-individuals/index.html, accessed 9/10/2018.

[6] The Rehabilitation Act of 1973 **prohibits discrimination on the basis of disability in programs conducted by Federal agencies**, in programs receiving Federal financial assistance, in Federal employment and in the employment practices of Federal contractors. The Americans with Disabilities Act of 1990 prohibits private sector employers who employ 15 or more individuals and all State and local government employers from discriminating against qualified individuals with disabilities in all aspects of employment. discrimination.

Wider choice of ICs suggests that more people with NB will be able to find a catheter that suits their needs and desires. The lucrative European market may serve as an impetus for innovation of new technology with the result that consumers in the US ultimately benefit from. Lack of knowledge of catheters limits the potential benefits of increasing IC variety.

Enabler 3. OTC availability of basic straight catheters

An extremely important enabler of well-being in people with NB is the ability to buy ICs OTC, giving consumers control over their fundamental ability to cath. OTC availability offsets the negative effects of a number cap on ICs reimbursed each month that does not fluctuate to meet individuals' changing life situations. Though sale of OTC ICs is a commonplace, the legality of the practice, in retail outlets in jurisdictions across the US or online is unclear. Lack of legal clarity undermines the solidity of this catheter security strategy.

Enabler 4. Centrality of the supplier

Our expectation in this study was that various payers, particularly insurers in the commercial space, would have catheter reimbursement policies that directly impacted consumer satisfaction and well-being. This scenario did not play out in the network described by our small group of participants. Rather, the supplier emerged as the actor positioned to make the wheels of the catheter acquisition process turn. Our participants described a functioning (though not without problems) catheter distribution system where suppliers and manufacturers were able to provide products and services. Products and services are then reimbursed by payers, both public and private, while satisfying consumer preference and demand for catheters with no out-of-pocket cost (e.g., absorbing co-pays). Though not the experience of our stakeholders, there are risks inherent in the central position the supplier holds in the IC distribution process. Particularly in the absence of an objective source of information to compare IC products. Beatrice's narrative demonstrating her supplier's attentiveness could also be interpreted as describing a supplier whose interest was to increase her profit by offering Beatrice a cheaper product or acting on an incentive from a manufacturer to give a certain product more exposure. Of course, both narratives can simultaneously apply. Beatrice's supplier can be motivated both by recognition of her client's possible need of a better product and a desire to increase profit. Again, creation of an information clearinghouse to help customers evaluate options would be desirable.

Limitations

Our study has several limitations. The sample of nine stakeholders is small. Participants were drawn from all the principal categories of actors identified with the US IC reimbursement ecosystem, however their experiences create a roughly-sketched view of just one possible network of people, things, and abstractions governing IC reimbursement. A different sample of individuals might present a differently configured network. The uniformly high degree of self-efficacy, passion, and strength of self-advocacy skills among our participants may have led to their predominantly good outcomes. For consumers with fewer personal and material resources, the outcomes may have looked different. Notably, we did not interview anyone whose catheters were primarily provided through Medicaid. Perspectives and observations described in this article reflect peoples' personal interpretation of their experiences and may or may not be objectively correct. No participant had experience with the third main category (code) for reimbursement, namely, coudé catheters.

Conclusions and Recommendations

Differentiation of HCs, or coated ICs more generically, is supported by the literature and would seem to be a reform whose time has come. Requiring people with NB to experience two UTIs before having access to UTI-preventing ICs disagrees with the general population perspective on illness prevention and antibiotic therapy minimization. Further, these current eligibility criteria neglect the psychosocial importance of closed catheters, especially for women aligned with principles of Disability-Competent-Care. Persons with NB, already at high risk for UTI, should be eligible for the HC and closed systems if they prefer without having to first experience life-threatening illness. Monthly allocation of catheters should be individualized and the creation of a back-up supply allowed. The OTC availability of ICs is an important source of catheter security and provides individuals control over emptying their bladders that should continue. Information on current and emerging catheter technologies should be readily available.

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