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## Development of a patient preference survey for wearable kidney replacement therapy devices

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### Key Points:

\*We included the risks of serious bleeding and serious infection based on patient concerns and regulator input about future trial endpoints.

\*The survey will estimate maximal acceptable risks for serious bleeding and infection and willingness to wait for devices with lower risk.

### Abstract:

Background: Recent innovations have the potential to disrupt the current paradigm for kidney failure treatment. The U.S. Food and Drug Administration is committed to incorporating valid scientific evidence about how patients weigh the benefits and risks of new devices into their decision-making, but to-date, premarket submission of patient preference information (PPI) has been limited for kidney devices. With input from stakeholders, we developed a survey intended to yield valid PPI, capturing how patients trade off the potential benefits and risks of wearable dialysis devices and in-center hemodialysis. Methods: We conducted concept elicitation interviews with individuals receiving dialysis to inform instrument content. After instrument drafting, we conducted two rounds of pre-test interviews to evaluate survey face validity, comprehensibility, and perceived relevance. We pilot-tested the survey with in-center hemodialysis patients to further assess comprehensibility and usability. Throughout, we used participant input to guide survey refinements. Results: Thirty-six individuals receiving in-center or home dialysis participated in concept elicitation (N=20) and pre-test (N=16) interviews. Participants identified reduced fatigue, lower treatment burden, and enhanced freedom as important benefits of a wearable device, and many expressed concerns about risks related to device disconnection—specifically bleeding and infection. We drafted a survey that included descriptions of the risks of serious bleeding and serious infection as well as an assessment of respondent willingness to wait for a safer device. Input from pre-test interviewees led to various instrument modifications including treatment descriptions, item wording, and risk level explanations. Pilot testing of the updated survey among 24 in-center hemodialysis patients demonstrated acceptable survey comprehensibility and usability, although 50% of patients required some assistance. Conclusions: The final survey is a 54-item web-based instrument that will yield estimates of the maximal acceptable risk for the described wearable device and willingness-to-wait for wearable devices with lower risk.

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## **Development of a patient preference survey for wearable kidney replacement therapy devices**

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## KEY POINTS

- We included the risks of serious bleeding and serious infection based on patient concerns and regulator input about future trial endpoints.
- The survey will estimate maximal acceptable risks for serious bleeding and infection and willingness to wait for devices with lower risk.

## ABSTRACT

**Background:** Recent innovations have the potential to disrupt the current paradigm for kidney failure treatment. The U.S. Food and Drug Administration is committed to incorporating valid scientific evidence about how patients weigh the benefits and risks of new devices into their decision-making, but to-date, premarket submission of patient preference information (PPI) has been limited for kidney devices. With input from stakeholders, we developed a survey intended to yield valid PPI, capturing how patients trade off the potential benefits and risks of wearable dialysis devices and in-center hemodialysis.

**Methods:** We conducted concept elicitation interviews with individuals receiving dialysis to inform instrument content. After instrument drafting, we conducted two rounds of pre-test interviews to evaluate survey face validity, comprehensibility, and perceived relevance. We pilot-tested the survey with in-center hemodialysis patients to further assess comprehensibility and usability. Throughout, we used participant input to guide survey refinements.

**Results:** Thirty-six individuals receiving in-center or home dialysis participated in concept elicitation (N=20) and pre-test (N=16) interviews. Participants identified reduced fatigue, lower treatment burden, and enhanced freedom as important benefits of a wearable device, and many expressed concerns about risks related to device disconnection—specifically bleeding and infection. We drafted a survey that included descriptions of the risks of serious bleeding and serious infection as well as an assessment of respondent willingness to wait for a safer device.

Input from pre-test interviewees led to various instrument modifications including treatment descriptions, item wording, and risk level explanations. Pilot testing of the updated survey among 24 in-center hemodialysis patients demonstrated acceptable survey comprehensibility and usability, although 50% of patients required some assistance.

**Conclusions:** The final survey is a 54-item web-based instrument that will yield estimates of the maximal acceptable risk for the described wearable device and willingness-to-wait for wearable devices with lower risk.

## INTRODUCTION

Kidney replacement therapy (KRT) technology has been stagnant for decades. The majority of people with kidney failure are treated with in-center hemodialysis, a therapy with debilitating side effects and burdensome thrice-weekly clinic visits.<sup>1</sup> However, catalyzed by U.S. regulatory reform and the Kidney Innovation Accelerator (KidneyX) prize competition,<sup>2, 3</sup> there has been unprecedented KRT research and development in recent years.<sup>4</sup> It is anticipated that this focus will yield innovations in wearable and implantable KRT technologies – products that could disrupt the current KRT paradigm and improve the lives of people affected by kidney failure.

In making regulatory approval decisions for medical devices, the US Food and Drug Administration (FDA) Center for Devices and Radiologic Health (CDRH) considers whether submitted evidence provides reasonable assurance that a device is safe and effective for its intended use.<sup>5</sup> In addition, and when the supporting information meets FDA specifications for valid scientific evidence, the FDA may consider patient perspectives of risk tolerance and perceived benefits in their assessment of the device's benefit-risk profile.<sup>6, 7</sup> For example, patient preference information (PPI), defined by CDRH as “qualitative or quantitative assessments of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions,”<sup>6</sup> was used to support the labeling expansion of a home hemodialysis system to permit solo use during waking hours.<sup>8</sup> Valid PPI are generated from well-designed and -conducted studies that use “fit-for-purpose” data collection strategies and can be used by regulators to prioritize outcomes for clinical trials, establish patients' perspectives on minimum acceptable performance thresholds (i.e., minimal acceptable benefit and maximal acceptable risk), and inform acceptable levels of uncertainty for outcomes.<sup>6, 9</sup> Incorporating stakeholder perspectives, particularly patient voices, into the process of designing PPI studies is critical to ensuring the relevance and quality of the resultant data.

With an overall objective of supporting the incorporation of patient perspectives into regulatory decision-making regarding KRT technologies, we partnered with patients, regulators, innovators, and clinicians to develop a survey intended to yield valid, regulatory-grade PPI, capturing how patients trade off the potential benefits and risks of KRT devices.

## **MATERIALS AND METHODS**

### **Overview**

A steering committee provided overall project guidance and was supported by a survey development workgroup. Steering committee and workgroup members included patients (n=4), preference experts (n=4), regulators (n=7), and academic nephrologists (n=4) (**Supplemental Table S1**). After conducting an environmental scan of KRT research and development (**Supplemental Table S2**), the committee selected wearable KRT devices (both hemodialysis and peritoneal dialysis) as the alternative treatment and in-center hemodialysis as the reference treatment for the PPI survey. Wearable devices were selected due to their potential for near-term market readiness, and because patient preferences play an important role in the adoption of such innovations.<sup>6</sup>

Following recommendations for formative qualitative research to inform the development of quantitative preference instruments, we used a two-staged approach for survey development that included concept elicitation and subsequent content refinement based on target population input.<sup>6, 9-11</sup> We considered the FDA-recommended qualities of patient preference studies<sup>6</sup> (**Table 1**) and followed a 5-step process: 1) conducting concept elicitation interviews; 2) constructing a draft survey; 3) pre-testing and responsively updating the survey; 4) pilot testing the survey in the in-center hemodialysis setting; and 5) planning survey fielding (**Figure 1**). The RTI Institutional Review Board deemed this research exempt from further review (Study #00021084).

### **Concept Elicitation Interviews**

Concept elicitation interviews captured patient perspectives on potential benefits and risks of wearable devices and characterized patient knowledge and questions about such devices. Experienced interviewers used a semi-structured interview guide (**Supplemental Table S3**) to conduct telephone-based interviews in May and June 2020. Most interviews (n=18) were conducted as dyads (i.e., 2 participants at a time). Dyadic interviewing falls between individual interviews and focus groups on the spectrum of interactive qualitative data collection and allows interviewees to react to and interact with each other, enhancing the depth of data collected.<sup>12</sup> We selected a virtual approach due to COVID-19 safety concerns. We stopped interviews when no new benefits or risks emerged after 3 consecutive interviews (data saturation).

We recruited participants via telephone and email, using a research firm's national database that includes individuals with kidney disease as the recruitment source. Individuals were eligible to participate if they were  $\geq 22$  years old (FDA definition of adulthood<sup>13</sup>), English-speaking, and currently receiving in-center hemodialysis, home hemodialysis, or peritoneal dialysis. We used purposive sampling to ensure representation of individuals of varying sociodemographic characteristics, education levels, dialysis modalities, and levels of patient activation as measured by the Consumer Health Activation Index.<sup>14</sup> Participants received \$75 remuneration.

### **Survey Instrument Construction**

We selected the threshold technique as the analytic approach to quantifying patient preferences given its simpler design and smaller sample size requirement (compared to discrete choice experiments), capacity to produce individual respondent level (vs. sample level) estimates of maximal acceptable risk, and precedent for use in regulatory PPI studies.<sup>9, 15-17</sup> We then constructed a draft instrument using concept elicitation interview findings to inform treatment descriptions and risks/benefits (attributes). We relied on published literature to quantify risk estimates for each treatment (**Supplemental Table S4**). In addition, we interviewed



individuals from teams (industry and academic) actively engaged in developing wearable dialysis devices to inform our device descriptions and graphics. We revised the instrument based on iterative input from steering committee members, patient advisors, industry representatives, and content experts.

### **Survey Pre-Test Interviews**

After survey revision, we performed two rounds of pre-test interviews with patients to assess survey face and content validities, as well as comprehensibility and relevance. Results from each round informed subsequent survey modifications. Experienced interviewers used a semi-structured interview guide (**Supplemental Table S3**) to conduct telephone-based interviews in October and November 2020. Prior to the interview, we mailed participants a paper copy of the survey instrument so they could view the device descriptions and graphics during the interview. The interviewers then used the think-aloud technique, a process by which participants verbalize their thoughts as they complete a task to obtain feedback on instructions, wording, response options, and graphics.<sup>18</sup> Interviews were approximately 90 minutes, and participants received \$100 remuneration.

We used the same participant selection criteria and recruitment source for pre-test interviews as for concept elicitation interviews. We used purposive sampling to include individuals of varying sociodemographic characteristics, dialysis treatment modalities, and comfort with technology. Consistent with expert recommendations, our target sample size was 5-10 participants per round,<sup>19</sup> and we stopped recruitment upon reaching data saturation.

### **Survey Pilot Test**

Following responsive survey revisions, a professional, native Spanish-speaker translated the survey into Spanish, refining in response to pre-testing with 5 Spanish-speaking dialysis patients. The goal of the translation process was conceptual equivalence.<sup>20</sup> We then converted the survey from paper to a web-based format and conducted a pilot test to assess the feasibility of survey administration in the in-center hemodialysis setting. Pilot test participants completed

the surveys on tablet computers during hemodialysis treatments while research coordinators recorded observations in structured field notes on assistance required, questions and/or comments, observed difficulties (comprehension or technical), and survey completion time.

We used fliers and in-person approaches to recruit participants from 4 U.S. Renal Care-operated clinics in Alaska, Georgia, and Texas. Individuals were eligible to participate if they were  $\geq 22$  years old, English or Spanish-speaking, and had received in-center hemodialysis for  $\geq 3$  months. We used purposive sampling to identify individuals with varying technology comfort, over-sampling for those self-reporting less tablet computer experience. Participants received \$50 remuneration.

### **Analytic Approach**

We used descriptive statistics (count (%), mean ( $\pm$  standard deviation, SD) to report participant characteristics and pre- and pilot testing quantitative findings.

Interviews were audio-recorded and transcribed. We organized concept elicitation interview data by question and used directed content analysis to identify potential risks and benefits of wearable devices important to patients.<sup>21, 22</sup> Through iterative discussion, researchers resolved discrepancies and reached consensus. To evaluate question performance, we organized pre-test interview data by survey section (e.g., treatment and risk descriptions, risk/benefit trade-off questions, waiting time question). We also examined pilot test field notes to understand sources of participant challenges. We created overall summaries, which the study team collectively reviewed, along with accompanying notes, to confirm accurate data summation, and then made responsive survey updates.

## **RESULTS**

### **Participant Characteristics**

**Table 2** displays participant characteristics. We conducted 20 concept elicitation and 16 pre-test interviews with 17 (47%) in-center hemodialysis, 11 (31%) home hemodialysis, and 8

(22%) peritoneal dialysis patients. Participants ranged from 26 to 77 years of age, 16 (44%) were female, 9 (25%) had a high school or equivalent education or less, and 10 (28%) were of “low” patient activation.<sup>14</sup> Pilot test participants included 24 in-center hemodialysis patients who ranged from 34 to 72 years of age. Eleven (46%) were female, 14 (58%) had no more than a high school or equivalent education, and 5 (21%) had received in-center hemodialysis for <1 year. Notably, 12 (50%) reported using a computer or tablet computer never or rarely, and 5 (21%) reported being uncomfortable using a computer or tablet.

### **Concept Elicitation Interview Findings**

Of the 20 concept elicitation interviewees, 7 (35%) had heard of wearable KRT devices, and, after reviewing a description of such devices, 6 (30%) expressed strong interest in use, 13 (65%) expressed moderate interest, and 1 (5%) had no interest. Participants were asked to rank the potential benefits and downsides (risks) of a wearable device that were most important to them. For potential benefits, participants were most likely to rank “feel better and have more energy” (9 interviewees, 45%), “needing fewer medications” (6 interviewees, 30%), and “ability to drink more fluids” (6 interviewees, 30%) as first or second in importance. For potential downsides, participants were most likely to rank “catheter may become accidentally removed or disconnected” (18 interviewees, 90%) and “device may stop working” (12 interviewees, 60%) as first or second in importance. Specific participant concerns regarding catheter disconnection included pain, bleeding, and/or infection.

**Table 3** displays illustrative quotations. While participants were intrigued by wearable devices and enthusiastic about potential benefits—especially enhanced freedom—they wanted more information about device safeguards (e.g., disconnection alarms, remote monitoring), characteristics (e.g., size/weight, visibility), function (e.g., battery life, fluid storage), and effectiveness (e.g., clearance, fluid removal). Finally, participant interest in using a wearable device appeared to differ by treatment modality, with patients receiving in-center hemodialysis expressing more definitive interest in wearables, and people receiving home dialysis expressing

more moderate interest. All 3 peritoneal dialysis users who responded noted that their current modality offers benefits similar to those of a wearable device (e.g., flexible treatment schedule).

### **Survey Instrument Construction**

We selected serious bleeding and serious infection as the risks of interest, based on regulator input on the anticipated study endpoints for trials of wearable KRT devices as well as patient interviews revealing concern for device disconnection-related risks. Following draft instrument construction, input from patient advisors and external industry experts led to instrument updates including: 1) revision of the treatment graphics (e.g., added masks to in-center patient and healthcare professional, changed wearable device tubing color); 2) change in the weight of the wearable device from 5 to 5-10 pounds; 3) addition of information about safeguards for both treatment types; 4) specification that the device would be worn “most of the time, both day and night,” and 5) clarification of the risk denominator (i.e., risk over a year’s time).

### **Pre-Test Interview Findings**

We then pre-tested the survey with the target population. Overall, round 1 participants (N=7) displayed good comprehension of survey content with all responding correctly to questions about the two dialysis treatment types (i.e., wearable devices and in-center hemodialysis). Of the 7 participants, 6 (86%) understood the pictographs depicting the proportion of people who would experience the risks (bleeding or infection) in a year. Participant responses resulted in survey refinements to increase clarity (e.g., modifications to the treatment graphics and descriptions, clarification of terminology). Round 2 participants (N=9) also displayed good comprehension of survey content but 2 (22%) needed assistance understanding the comparator populations for the risk trade-off and wait time questions. In response, we added clarifying text to the relevant instructions. **Table 4** summarizes findings and responsive survey revisions.

### **Pilot Test Findings**

Of the 24 in-center hemodialysis pilot test participants, 16 (67%) completed the survey in English and 8 (33%) completed the survey in Spanish. Of the 24 participants, 12 (50%) required assistance with survey completion. Types of assistance provided included: navigating the tablet computer (e.g., advancing screens, tapping responses, scrolling), holding the tablet, and reading questions aloud for patients without their glasses or with severe visual impairment. The mean  $\pm$  SD time to completion was  $40 \pm 18$  minutes. Field notes suggested that survey completion during in-center hemodialysis was feasible for most patients, but some individuals, especially those with limited computer experience, required assistance.

### **Final Survey Instrument**

The final survey is a 54-item, web-based instrument that includes 1) risk tradeoff questions designed to quantify the levels of potential risks of serious bleeding and serious infection that patients are willing to accept in exchange for the benefits of the wearable KRT devices; 2) modified time tradeoff questions to determine respondents' discount rate for time until wearable devices are available; 3) comprehension questions to assess understanding of the presented information; and 4) background questions (**Figures 3 and 4; Supplemental Materials**). The survey will yield estimates of the maximal acceptable risk for the wearable device described and willingness-to-wait for wearable devices with lower risk in people living with kidney failure.

### **Future Survey Fielding**

The purposes of survey fielding are to assess the risk tolerance of patients for hypothetical wearable KRT devices and to demonstrate the feasibility of administration of a PPI survey to people receiving dialysis. Survey respondents will be adults with dialysis-dependent kidney failure who may be eligible and interested in enrolling in a clinical trial of a wearable KRT device. The survey will be fielded via partnerships with patient and dialysis organizations. Based on our pilot test experiences, we will use both self- and research team-assisted administration approaches, permitting survey completion during dialysis treatment if preferred by the patient.

Given that patient interviews suggested potential preference heterogeneity based on current dialysis modality, we will aim for a sample size to support subgroup analyses among patients using in-center hemodialysis, home hemodialysis, and peritoneal dialysis. Where sample size is sufficient, we will also examine the influence of other respondent characteristics (e.g., age, time on dialysis) on maximal acceptable risk.

## **DISCUSSION**

We described the development of a PPI survey that captures patient preferences for wearable KRT devices in comparison to in-center hemodialysis based on the potential benefits of the treatments and their potential risks of serious bleeding and serious infection. We engaged diverse stakeholders throughout survey development and followed best practices in preference science to maximize the validity and scientific rigor of our final instrument. We intend for the survey and our development approach to serve as models in future endeavors to capture regulatory-grade PPI for other innovative KRT technologies.

According to FDA guidance, PPI can be useful in evaluating the benefit-risk profiles of medical devices in the setting of “preference sensitive” patient decisions in which 1) there are multiple treatment options with no clearly superior option for all patients, 2) evidence supporting one treatment option over another is uncertain, and 3) patients’ perspectives on the benefits and risks of a device vary within a population, or differ from those of healthcare professionals.<sup>6</sup> Our PPI survey addresses a “preference-sensitive” decision, as there is no KRT treatment option that is clearly superior for all patients, and patient views on KRT benefits and risks vary.<sup>23-27</sup>

While submission of PPI to the FDA is voluntary, such data may strengthen the FDA’s ability to identify important patient-perceived benefits and risks of devices, assess how patients tradeoff benefits and risks of devices, and also understand heterogeneity in patient preferences.<sup>6</sup> For example, we anticipate that findings from our survey may identify patient subpopulations with higher tolerance for wearable device risks (e.g., an individual’s current KRT modality may

influence their perceptions of risks). This highlights the importance of targeting a survey sample size large enough to support modality-based subgroup analyses.

Patient preference surveys using the threshold technique typically present two treatment options and two to three potential treatment risks.<sup>15, 17</sup> While inclusion of additional risks may be of scientific interest, it greatly increases respondent burden. Our survey thus considers two treatments, a wearable device and in-center hemodialysis, and systematically alters two potential risks: serious bleeding and serious infection—selected based on our interviews with the target population and input from regulators identifying these risks as key safety endpoints for clinical trials of wearable devices. The risk level at which respondents “switch” to the alternative treatment indicates the respondents’ relative strength of preference and can be used in decision analyses and clinical trial design.<sup>26-28</sup>

We acknowledge that the risks of serious bleeding and serious infection do not represent the totality of potential risk related to wearable devices. For example, frequent clotting poses a challenge to hemodialysis-based wearable functionality such that it may require significant amounts of anticoagulation to maintain pump function. Preference surveys capturing patient perspectives on the risks of blood loss from frequent system clotting vs. the risks of bleeding from anticoagulation-related complications may be important. Moreover, because detailed information about wearable devices is not yet available, our survey describes “hypothesized” peritoneal dialysis- and hemodialysis-based devices, as well as assumptions about their features, safeguards, and potential benefits. As such, we used composite risk estimates for bleeding and infection, yielding an average of wearable peritoneal dialysis- and hemodialysis-related risk. We anticipate that future PPI surveys for KRT innovations will be device-specific, supporting greater precision in assessing patient risk-benefit tradeoffs. Our developed survey will hopefully serve as a model for such future efforts.

Strengths of our study include involvement of diverse stakeholders, use of purposive sampling to capture perspectives from heterogeneous patients, and adherence to best practices

in preference science. Limitations relate to the lack of a specific wearable KRT device on which to focus the survey and absence of published data on wearable device risks of serious bleeding and serious infection. In addition, while we sought to represent the population as best as possible, the nature of our survey could preclude its applicability to all people treated with dialysis. We acknowledge that the risk and time trade-off questions are hypothetical and require abstract thought, which could make it difficult for some individuals to respond to the survey. Related, we selected a web-based format to support future computerized adaptive testing for varied risk and wait-time thresholds, potentially limiting survey accessibility to some patients. Similarly, the survey length could be a deterrent to some respondents. However, our pilot test showed that patients were able to complete the full survey and that most patients could complete it electronically when technology-related (not content) assistance was provided. In addition, our approach is consistent with FDA guidance to “measure preferences and perspectives on benefits and risks of *well-informed* patients.”

In conclusion, we described the stakeholder-engaged process of developing a PPI survey for wearable KRT devices. The next step is to assess the risk tolerance of patients for hypothetical wearable devices and to demonstrate the feasibility of administration of a PPI survey to people receiving dialysis by administering the survey to its target population.

## **DISCLOSURES**

J. Flythe reports the following: Consultancy: Fresenius Medical Care Medical Advisory Board; Astra Zeneca; Research Funding: NIH/NIDDK; NIH/NHLBI; PCORI; Robert Wood Johnson Foundation; Renal Research Institute (subsidiary of Fresenius Medical Care- North America); Honoraria: American Society of Nephrology; National Kidney Foundation; Numerous universities; and Advisory or Leadership Role: KDIGO Executive Committee (2020-); KHI Board of Directors (2019-); KHI Patient Preferences Project Chairperson (2019-); American Journal of Kidney Diseases Editorial Board (2017-2021 ); Clinical Journal of American Society of Nephrology Editorial Board (2017- ); Nephrology Dialysis and Transplantation Editorial Board, Hemodialysis Theme Editor (2018- ); Kidney Medicine Editorial Board (2019-); Kidney 360



Associate Editor (2019-). K. Cavanaugh reports the following: Consultancy: Kidney Health Initiative (KHI); Responsum Health; REATA Pharmaceuticals; Ownership Interest: HCA Healthcare; and Advisory or Leadership Role: National Kidney Foundation - KDQOI education committee; CJASN-Editorial board; AJKD-Editorial board; Medical Decision Making-Editorial board; Kidney360 - Associate Editor. D. Forfang reports the following: Employer: ASN Kidney Health Initiative (KHI); Consultancy: University of North Carolina Kidney Center, CareDX, Ardelyx Inc Scientific Advisory Board, ASN and Responsum., ASN, HSAG; Honoraria: National Kidney Foundation, ASN, HSAG ESRD Network #17; Advisory or Leadership Role: HSAG ESRD Network #17 Board Member; National Forum of ESRD Networks, Board Member; National Forum of ESRD Networks, Kidney Patient Advisory Council, Chair; Kidney Health Initiative, Patient Advisory Committee; National Kidney Foundation, SONG Group, European Association for Dialysis, Arbor Research and Unity Health Toronto OPPUS, UCSF Kidney Project Patient Advisor; and Other Interests or Relationships: Volunteer for The Forum of ESRD Networks as Kidney Patient Advisory Council Chair and Board Member; Volunteer for ESRD Network #17 as Patient Advisory Committee Chair and Network Board Member; Volunteer for the NKF as a member of their Public Policy Committee; Volunteer for the NKF as a Regional Leader of their Kidney Advocacy Committee, KHI PFPC Member. N. Gedney reports the following: Honoraria: University of Washington, IDEAs; ASN. R. Harris reports the following: Consultancy: Bayer; Nicoya; Fibrocor; Ownership Interest: Apple; Research Funding: Bayer; Patents or Royalties: eNOS db/db mouse; Advisory or Leadership Role: Kidney Health Initiative (paid); and Other Interests or Relationships: Kidney Health Initiative- Co-Chair, Board of Directors. F. Hurst reports the following: Employer: FDA / Center for Drug Evaluation and Research; and Other Interests or Relationships: Us govt employee. C. Mansfield reports the following: Employer: RTI Health Solutions; and Other Interests or Relationships: I am an employee of RTI Health Solutions, which receives funding from for-profit pharmaceutical companies to conduct research. C. Neuland reports the following: Advisory or Leadership Role: I have been a member of the Board of Directors for the Kidney Health Initiative, representing FDA, CDRH, during this time period. A. Saha reports the following: Employer: U.S. Food and Drug Administration. C. Soloe reports the following: Employer: RTI International. G. Squillaci reports the following: Consultancy: The Griff Group. M. Tarver reports the following: Employer: FDA/CDRH. K. Treiman reports the following: Employer: RTI International. M. Unruh reports the following: Consultancy: Cara Therapeutics to chair of Data Monitoring Committee. Consulting agreement between Cara and the University of New Mexico.; Research Funding: DCI; and Honoraria: Renal Research Institute, NKF, and ASN for honoraria related to lectures. M. West

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Jennifer Flythe: Conceptualization; Funding acquisition; Investigation; Methodology; Project administration; Supervision; Visualization; Writing - original draft; Writing - review and editing. Grace Squillaci: Conceptualization; Funding acquisition; Project administration; Writing - review and editing. Carol Mansfield: Conceptualization; Formal analysis; Funding acquisition; Investigation; Methodology; Supervision; Writing - review and editing. Cindy Soloe: Data curation; Formal analysis; Methodology; Writing - review and editing. Katherine Treiman: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Validation; Writing - review and editing. Dallas Wood: Data curation; Formal analysis; Methodology; Project administration; Software; Validation; Writing - review and editing. Frank Hurst: Conceptualization; Writing - review and editing. Carolyn Neuland: Conceptualization; Writing - review and editing. Anindita Saha: Conceptualization; Writing - review and editing. Derek Forfang: Conceptualization; Writing - review and editing. Nieltje Gedney: Conceptualization; Writing - review and editing. David White: Conceptualization; Writing - review and editing. Caroline Wilkie: Conceptualization; Writing - review and editing. Raymond Harris: Conceptualization; Funding acquisition; Writing - review and editing. Kerri Cavanaugh: Conceptualization; Writing - review and editing. Mark Unruh: Conceptualization; Writing - review and editing. Melissa West: Conceptualization; Funding acquisition; Project administration; Writing - review and editing. Murray Sheldon: Conceptualization; Supervision;

Writing - review and editing. Michelle Tarver: Conceptualization; Supervision; Writing - review and editing.

## SUPPLEMENTAL MATERIAL

Supplemental Table S1. Steering committee members

Supplemental Table S2. Environmental scan of KRT research and development activities

Supplemental Table S3. Representative concept elicitation and pre-test interview questions

Supplemental Table S4. Survey risk levels and supporting evidence

Final patient preference survey

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## **TABLES**

**Table 1.** FDA-recommended qualities of patient preference studies.<sup>6</sup>

<b>Recommended quality (definition)</b>	<b>Consideration in survey development</b>
<b>Patient Centeredness</b> (Ensure that the patient, not the health care professional is focus of the study)	<ul style="list-style-type: none"> <li>• Patient input</li> <li>• Concept elicitation interviews</li> <li>• Pre-testing</li> </ul>
<b>Representativeness of the Sample and Generalizability of Results</b> (Measure the preferences of a representative sample of adequate size)	<ul style="list-style-type: none"> <li>• Pilot testing</li> <li>• Fielding planning</li> <li>• Purposive sampling on specific respondent characteristics</li> </ul>
<b>Capturing Heterogeneity of Patients' Preferences</b> (Reflect preferences of patients from full spectrum of disease for which the device is intended to be used)	<ul style="list-style-type: none"> <li>• Concept elicitation interviews</li> <li>• Pre-testing</li> <li>• Purposive sampling on specific respondent characteristics</li> </ul>
<b>Established Good Research Practices</b> (Follow guidelines established by a recognized professional organization)	<ul style="list-style-type: none"> <li>• All development steps aligned with ISPOR and Medical Device Innovation Consortium best practices<sup>29,30</sup></li> <li>• Involvement of PPI experts in study design</li> </ul>
<b>Effective Communication of Benefit, Harm, Risk, and Uncertainty</b> (Communicate the quantitative aspects of the health information in ways that the patient can understand and cognitively process this information)	<ul style="list-style-type: none"> <li>• Patient input</li> <li>• Survey construction using best practices</li> <li>• Pre-testing</li> <li>• Pilot testing</li> </ul>
<b>Minimal Cognitive Bias</b> (Minimize potential cognitive biases such as framing, anchoring, simplifying heuristics, or ordering effect)	<ul style="list-style-type: none"> <li>• Survey construction</li> <li>• Pre-testing</li> <li>• Pilot testing</li> </ul>
<b>Logical Soundness</b> (Test logic and consistency of presented data)	<ul style="list-style-type: none"> <li>• Patient input</li> <li>• Pre-testing</li> <li>• Pilot testing</li> </ul>
<b>Relevance</b> (Include critical aspects of harm, risk, benefit, and uncertainty, ensuring some consistency with endpoints from clinical studies of the device)	<ul style="list-style-type: none"> <li>• Concept elicitation interviews</li> <li>• Patient, regulator, and expert input</li> </ul>
<b>Robustness of Analysis of Results</b> (Ensure appropriate interpretation of the collected evidence with attention to understanding the potential sources for uncertainty)	<ul style="list-style-type: none"> <li>• Involvement of PPI experts in study design</li> </ul>
<b>Study Conduct</b> (Administer by trained research staff or, when self-administered, use a tutorial and quiz before answering questions to ensure adequate comprehension)	<ul style="list-style-type: none"> <li>• Survey construction</li> <li>• Pilot testing</li> <li>• Fielding planning</li> </ul>
<b>Comprehension by Study Participants</b> (Ensure that participants fully understand the harm, risk, benefit, and uncertainty and other medical information being communicated to them)	<ul style="list-style-type: none"> <li>• Patient input</li> <li>• Pre-testing</li> <li>• Pilot testing</li> </ul>

Abbreviations: FDA, Food and Drug Administration; PPI, patient preference information.

**Table 2.** Characteristics of patient participants in survey development.<sup>a</sup>

Survey development participants (N=60)			
Characteristic	Concept elicitation interviews (n=20)	Survey pre-test interviews (n=16)	Survey pilot test (n=24) <sup>e</sup>
<b>Age (years)</b>			
22 - 40	5 (25%)	5 (31%)	1 (4%)
41 - 52	6 (30%)	2 (13%)	4 (17%)
53 - 65	6 (30%)	6 (38%)	10 (44%)
66-75	0	1 (6%)	8 (35%)
≥76	3 (15%)	2 (13%)	0
<b>Gender</b>			
Male	10 (50%)	10 (63%)	13 (54%)
Female	10 (50%)	6 (38%)	11 (46%)
<b>Race / ethnicity</b>			
Black, non-Hispanic	8 (40%)	7 (44%)	4 (17%)
Asian, non-Hispanic	1 (5%)	0	0
Caucasian, non-Hispanic	9 (45%)	5 (31%)	7 (29%)
Hispanic or Latino	2 (10%)	4 (25%)	13 (54%) <sup>d</sup>
<b>Education level</b>			
Less than high school	0	0	6 (25%)
High school or equivalent <sup>b</sup>	6 (30%)	3 (19%)	8 (33%)
Associates degree/ trade school	1 (5%)	3 (19%)	0
Some college	8 (40%)	0	7 (29%)
College graduate	2 (10%)	1 (6%)	3 (13%)
Postgraduate	3 (15%)	2 (13%)	0
<b>Census region</b>			
Northeast	2 (10%)	0	0
South	8 (40%)	10 (63%)	20 (83%)
Midwest	6 (30%)	5 (31%)	0
West	4 (20%)	1 (6%)	4 (17%)
<b>Current dialysis modality</b>			
In-center hemodialysis	9 (45%)	8 (50%)	24 (100%)
Home hemodialysis	6 (30%)	5 (31%)	0
Peritoneal dialysis	5 (25%)	3 (19%)	0
<b>Time on dialysis (any modality)</b>			
3 months - 1 year	--	3 (19%)	5 (21%)
>1 year	--	13 (81%)	19 (79%)
<b>Time on current dialysis modality</b>			
<1 year	6 (30%)	3 (19%)	--
1-2 years	3 (15%)	4 (25%)	--
≥3 years	11 (55%)	9 (56%)	--
<b>Patient activation<sup>c</sup></b>			
Low	6 (30%)	4 (25%)	--
Medium	9 (45%)	10 (63%)	--
High	5 (25%)	2 (12%)	--

<sup>a</sup> Values are presented as n (%). All characteristics were patient-reported. "--" indicates that the data element was not collected. We recruited different individuals for each stage of development. There is no overlap in participants across concept elicitation interviews, survey pre-test interviews, and survey pilot test.

<sup>b</sup> Completion of high school degree or Tests of General Educational Development (GED).

<sup>c</sup> Assessed using the Consumer Health Activation Index.<sup>14</sup>

<sup>d</sup> 8 (33%) completed the survey in Spanish.

<sup>e</sup> Age value was missing for one pilot test participant (Age n=23).



**Table 3.** Illustrative quotations about wearable KRT devices from concept elicitation interview participants.

Domain/ Responses	Participant quotation (current dialysis modality)
<b>Knowledge</b>	
<i>Heard of wearables</i>	“I heard that it is pretty much just like a PD machine, and it dialyzes as you go, and it’s battery-operated... It allows you to be not worried about going into a center.” (ICHHD)
<i>Not heard of wearables</i>	“For dialysis, no. But I am a diabetic, and I do have a wearable continuous meter.” (PD) “Not this type of wearable device. Heard of something like a pacemaker.” (HHD)
<b>Initial reactions</b>	
<i>Strong interest</i>	“It sounds 100% great. When will it be available?” (ICHHD) “I would be very interested... it means I wouldn’t have to get up every other day and go into dialysis. It would be more convenient. I could get out and do what I want to do.” (ICHHD) “If I could have a device in a backpack that I can make discrete that would allow me to travel, I would definitely do it.” (HHD)
<i>Moderate interest</i>	“I actually think it’s great, but it depends if you are OK carrying the device with you... it can be more tiring carrying the device than you expect.” (ICHHD) “Theoretically, I’d be very interested in it, but I would have to know a whole lot more about the actual device... But the idea of having more freedom to be able to do stuff and not being tethered to the machine as long as I am almost every day, is very appealing.” (HHD) “I would be interested to see how it goes. I never want to be the first one to use something. I would wait on the sidelines for a good while.” (PD)
<i>No interest</i>	“I accepted the fact that I’m on dialysis, that I have to do dialysis to stay alive. No, not for me... Plain and simple, I would not be interested in it at all.” (ICHHD)
<b>Potential benefits<sup>a</sup></b>	
<i>More freedom/ ability to be active</i>	“Just a general overall increased quality of life.” (ICHHD) “You’re not tied down three times a week sitting on a chair and not [using] one of your arms. To me, it sounds like it could be something very positive.” (ICHHD) “The biggest benefit would be freedom from the machine. You kind of normalize dialysis, but the reality is that you got to do it to stay alive. So, you fit that schedule into your life.” (HHD) “Mobility. Being able to move around and get things done without having to stay in one room... It [would] just [be] a blessing... if it’s able to give me a little bit more freedom.” (PD)
<i>More independence</i>	“Being self-sufficient would be the ultimate benefit.” (ICHHD) “Well, depending on the machine and how it’s actually designed... to be able to be more self-sufficient and independent, to not have to be stuck in my house all day long...” (HHD)
<i>Fewer symptoms</i>	“I experience dizziness, shortness of breath, fainting, so [better symptom control] is important.” (ICHHD) “...fewer symptoms is really important because, for me, I’ve had episodes where I have a sudden blood pressure drop... and my stomach starts hurting, and I start sweating. And I start getting really short of breath, and I feel like I’m going to faint. My heart starts racing, and it’s a pretty painful and a little scary. It’s almost like a near death experience.” (PD)
<i>Fewer medications/ diet restrictions</i>	“Needing fewer medications and better control of blood pressure are close to the top of the list for me, because... I’m on four different blood pressure medications, and it’s a fight to keep my blood pressure down.” (ICHHD) “Not taking the phosphate binders would be a benefit. They are big pills.” (HHD) “Being on dialysis and having a very strict diet on top of being diabetic is stressful. So, if I’m able to eat a little bit more things that I would like and drink a little bit more because it’s hot in the summer... without it actually causing harm to my body, then that’s a benefit.” (PD)
<b>Potential harms or downsides<sup>a</sup></b>	
<i>Infection</i>	“I worry about infection. I have an auto-immune condition so I’m more vulnerable.” (ICHHD) “My biggest concern would be the infection... with catheters. I had infections with [my dialysis catheter]... which was very annoying, very painful, and potentially extremely dangerous. I would be very worried about any kind of wearable device that was attached to a hemodialysis catheter. I’d also wonder, it would probably have to be a chest catheter as well I assume, or neck. That certainly would worry me.” (HHD) [Reflecting on experience with peritonitis]... “Yeah, I had to stay in the hospital. They filled me up with antibiotics. I don’t want to go through that no more.” (PD)
<i>Device disconnection</i>	“I’ve had needles pulled out on accident in hemodialysis, and the amount of blood that came out of those little holes was a lot. I mean it was like a murder scene. Now imagine a tube... that you guys are probably going to be using. You could bleed out. And you can

	<p>catch it on things. And also [get] an infection.” (ICHHD)</p> <p>“The catheter becoming accidentally removed if it’s connected to the bloodstream. This’ll cause bleeding, pain, and possible infection or even bleeding out. Especially if you’re on heparin or something. I mean forget it.” (ICHHD)</p> <p>“Catheter may become accidentally removed or disconnected...that is really scary.” (PD)</p>
<i>Lack of supervision</i>	<p>“...if you ever had a problem, you’re not with any kind of professionals that can fix the problem.” (ICHHD)</p> <p>“So, if it stopped, I’d want to be around somebody. I’d want to be able to get to my dialysis center or if you were out of town then what do you do?” (ICHHD)</p>
<i>Feeling self-conscious</i>	<p>“...when I work, I don’t want things getting in my way and, in certain social settings, that’s kind of a downfall. It’s like, I’m sorry, but people do look down on people that are handicapped. Somebody in a wheelchair, or somebody’s got a big old machine or oxygen in their nose. And if you trying to do work, you’re trying to give them business...You might lose an account because people discriminate, and they don’t say why. I am a freelancer. And if I go to a client and then they see that, this tube and a machine on me, they’re not going to pick me again because they think I’m too sick to do the job. That’s why I don’t mind going to the center, because once I’m out of there, nobody knows I have dialysis.” (ICHHD)</p> <p>“I’m still young. I don’t necessarily want to walk around with the tube hanging and people asking questions.” (HHD)</p>
<i>Return to clinic when device not working</i>	<p>“Then, [the] device may stop working, and you have to adjust your mind to going back to in-center. That just becomes a disruption, re-thinking everything, trying to get the schedule that you need versus the schedule they can give you.” (HHD)</p> <p>“[What would be of most concern is] when something breaks with the device and getting it fixed and restoring regular treatment.” (PD)</p> <p>“...if [the device stops working], you may need to go to another form of dialysis for a period of time. That one could be tough. Like I said, it’s a big change, a big risk going into the clinic if that’s the one that you have to do.” (PD)</p>
<i>Concerns about device effectiveness</i>	<p>“For me, it all depends on its effectiveness. What’s the point of it if it’s not as effective and requires more maintenance and care than what I have to do [at] my three times a week, three hours a day center?” (ICHHD)</p> <p>“I would question how the machine knows how much fluid to take off. Because if you take too much, then you end up cramping...Then if you don’t take enough, you end up getting sick and possibly end up in the hospital.” (ICHHD)</p>
<i>Concerns about clinician knowledge of the device</i>	<p>“I would just hope that they would have the healthcare professionals properly trained so that it won’t make us feel like outcasts when we have a problem [with the device].” (PD)</p> <p>“Trying to imagine dealing with a hospital situation with a wearable artificial kidney would be very, very scary because they won’t know anything about it. They’ll want to put you onto what they know, which is going to be your standard in-center thing. They won’t know how to deal with it. It would be the scariest thing I could imagine having to deal with.” (HHD)</p>
<b>Comparison to current modality<sup>b</sup></b>	
<i>Wearable better</i>	<p>“It would be a huge improvement in quality of life, I wouldn’t have to worry about fatigue half the week, I wouldn’t have to worry about nausea and not being able to eat.” (ICHHD)</p> <p>“I would try it right away. It would help me to get back to school. I’m keeping a job offer waiting. I mean, this would just help me to get back into those things, versus what I’m doing right now. Let’s say you’ve got a meeting late in the night, and you’ve got an early morning class the next day... Sometimes your schedule is just that busy, and so this [device] helps to be able to do that.” (PD)</p>
<i>Unsure</i>	<p>“I think it could possibly be better even though it has its downsides.” (ICHHD)</p> <p>“It sounds like it is less painful. You don’t have to stick yourself with needles. But I think I would stick to what I am doing.” (HHD)</p> <p>“Advantages with PD and wearables are similar because you do PD at home. So, it’s similar to the wearable because your life isn’t completely revolving around treatment.” (PD)</p>

<sup>a</sup> Potential benefit/harm mentioned by at least 2 participants. Potential benefits mentioned by 1 participant were better blood cleaning (HHD) and fewer supplies (HHD). Potential downsides mentioned by 1 participant were cost (ICHHD) and always having something attached to you (PD).

<sup>b</sup> No participants identified their current dialysis modality as definitively better than a wearable device. No PD or HHD participants identified a wearable device as definitively better than their current dialysis modality.

**Table 4.** Representative pre-test interview findings and survey updates organized by select FDA-recommended qualities of PPI studies<sup>6, a</sup>

Round 1 Interview Findings (N=7)	Survey Updates	Round 2 Interview Findings (N=9)	Survey Updates
<b><i>Patient Centeredness</i></b>			
Considered risks (serious bleeding and infection) important to their KRT decision-making	N/A	Consistent with Round 1	N/A
Found treatment descriptions easy to understand (see minimal cognitive bias)	N/A	Consistent with Round 1	N/A
<b><i>Effective Communication of Benefit, Harm, Risk, and Uncertainty</i></b>			
Displayed good understanding of the potential risks and benefits of the treatments	N/A	Displayed good understanding of the potential risks and benefits of the treatments	N/A
All but 1 participant displayed good understanding of the pictorial representation of risk <sup>b</sup>	N/A	Displayed good understanding of the pictorial representation of risk	N/A
		Misunderstood the risk comparator to be the average person (vs. other dialysis patients)	Underlined the phrase “other dialysis patients” to emphasize comparator
<b><i>Minimal Cognitive Bias</i></b>			
Indicated that the in-center HD description was accurate	N/A	Consistent with Round 1	N/A
Indicated that the wearable description was straight-forward and understandable	N/A	Raised specific questions about the wearable (e.g., battery life, fluid storage, cleaning)	Added that the descriptions are of wearables in general and that features may vary by device
Found the wearable graphic helpful in showing the different ways could carry the device	N/A	Noted that the wearable graphic made the device look inconvenient and questioned whether they would want to use it	No change as participants understood the graphic
<b><i>Comprehension by Study Participants</i></b>			
Desired more information about patient monitoring and caring for the wearable in the comparison table of wearables and in-center HD	Added information about patient monitoring and device care to the comparison table	Indicated that the comparison table was understandable and sufficient	N/A
Expressed unfamiliarity with the term “peritoneum”	Added definition of term	Expressed understanding of all terminology	N/A
		Thought waiting time might be on current dialysis modality (vs. in-center HD) in the time tradeoff question <sup>c</sup>	Clarified the instructions by adding text to emphasize the assumption of in-center HD use while waiting for Device B
Exhibited difficulty understanding longer, complex sentences	Shortened and simplified sentence structure.	Exhibited sufficient understanding	N/A

<sup>a</sup> Based on FDA PPI guidance document.<sup>6</sup> Some interview findings apply to more than one FDA-recommended quality (e.g., input on treatment graphics and descriptions applicable to minimal cognitive bias and comprehension by study participants).

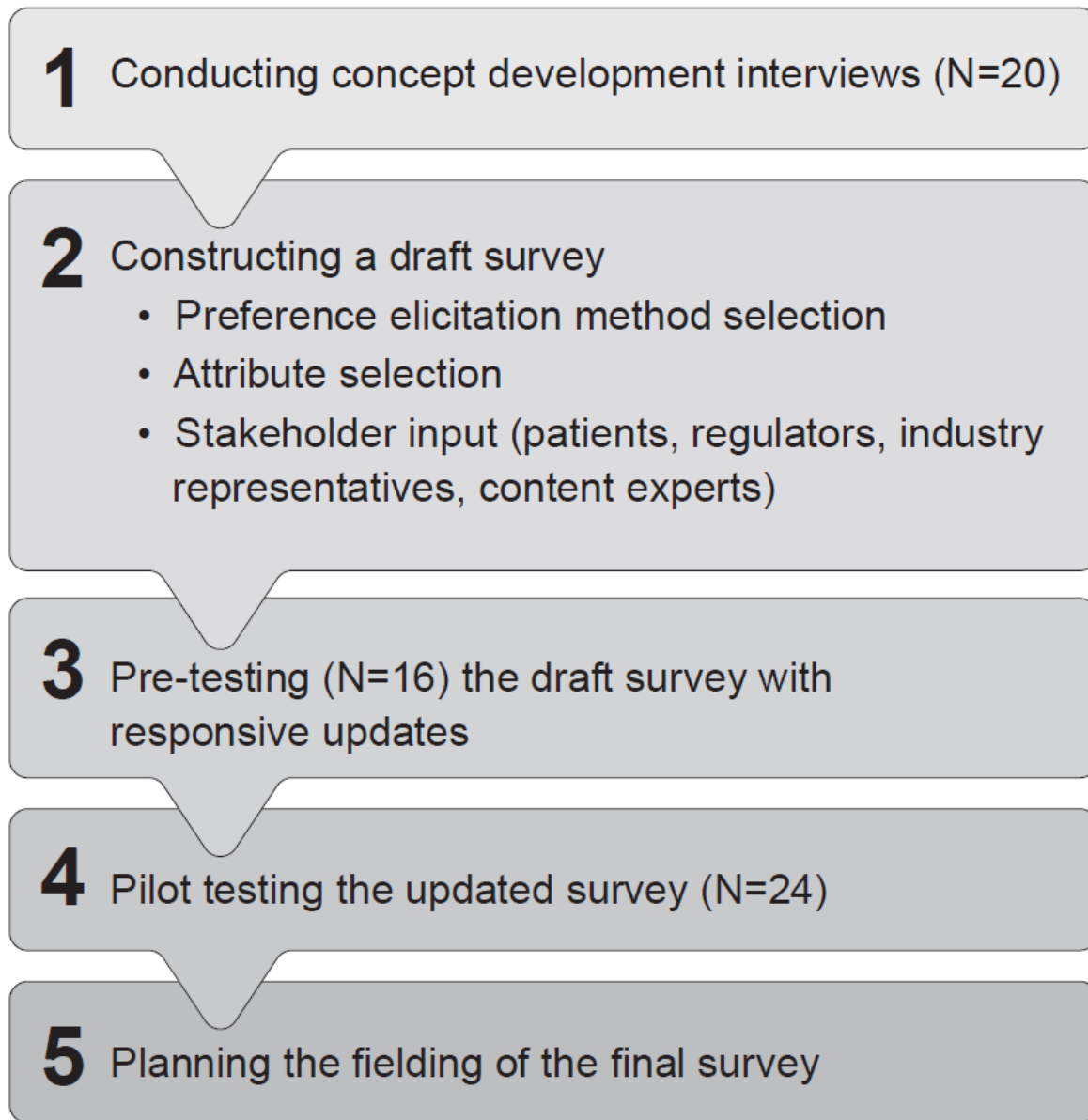
<sup>b</sup> No changes were made in response to this finding given understanding by all other participants and use of best practices in risk communication (e.g., use of text and pictures, absolute scales). This is consistent with FDA guidance that PPI studies “should aim to measure preferences and perspectives on benefits and risks of well-informed patients.”<sup>6</sup>

<sup>c</sup> Time trade-off questions were not included in Round 1 interviews as they were under development at the time.

Abbreviations: HD, hemodialysis; KRT, kidney replacement therapy; N/A, not applicable.

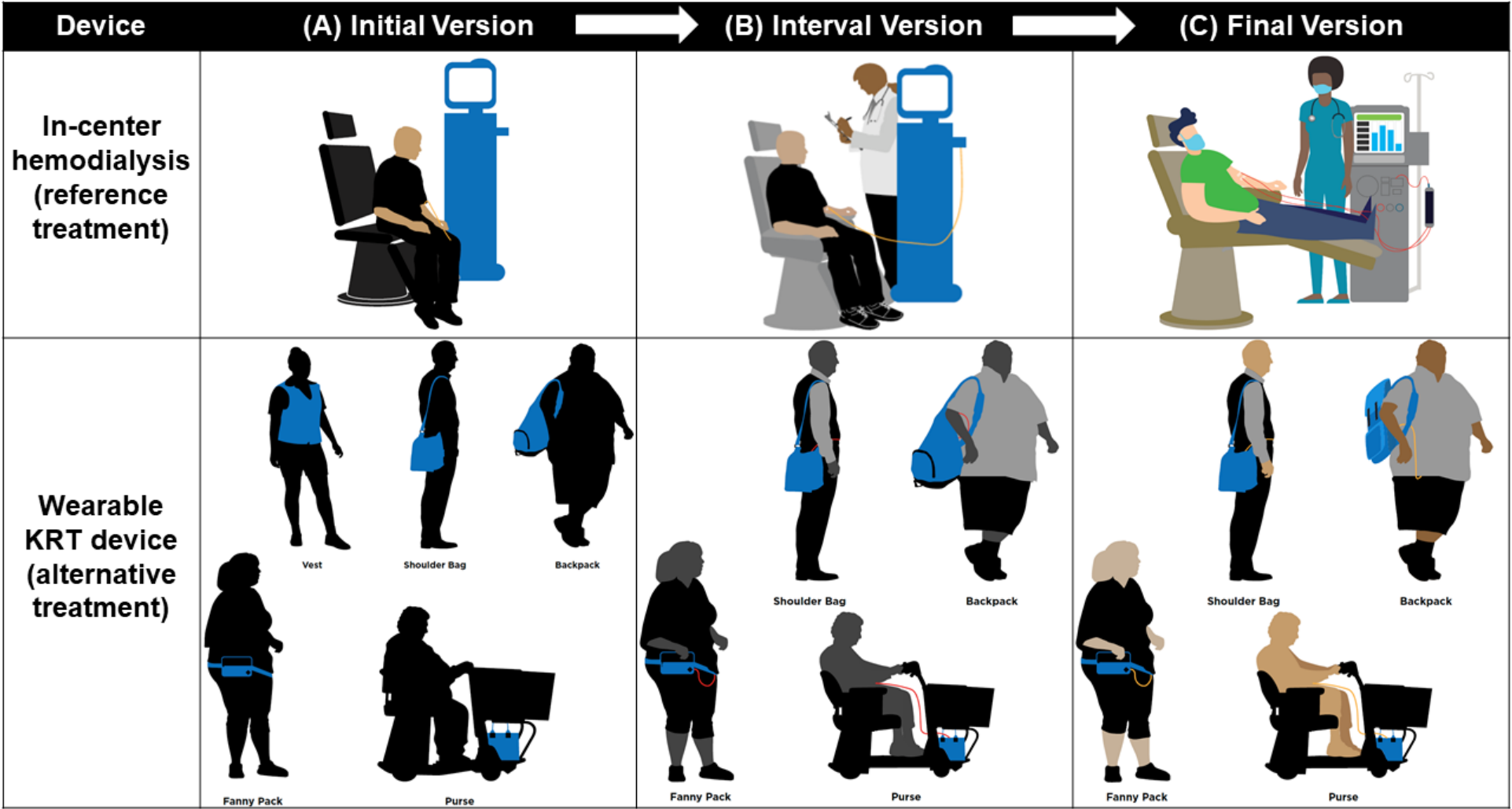
## **Figures**

**Figure 1.** Survey development process.



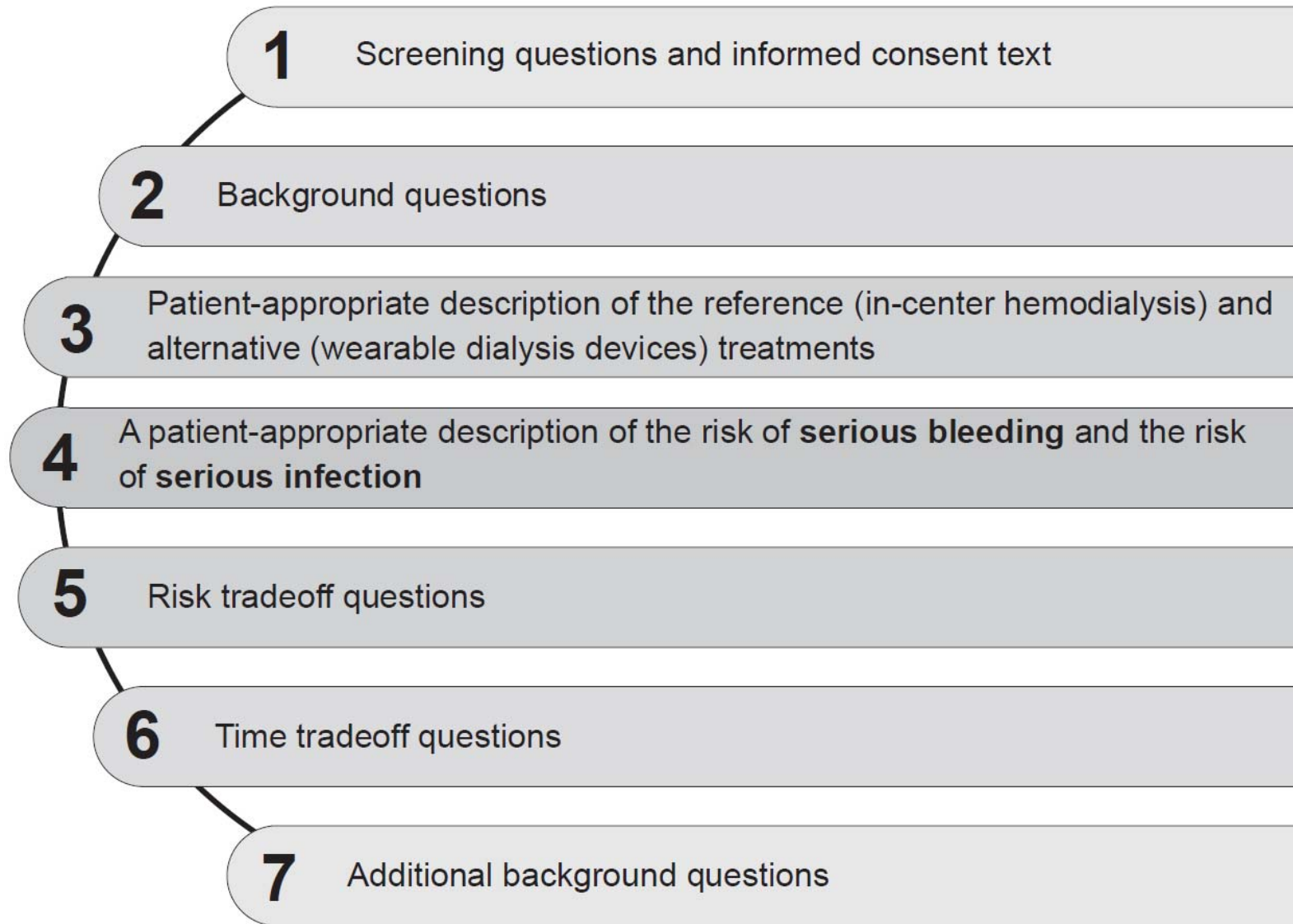
Survey development involved a 5-step process: 1) conducting concept elicitation interviews; 2) constructing a draft survey; 3) pre-testing and responsively updating the survey; 4) pilot testing the survey in the in-center hemodialysis setting; and 5) planning final survey fielding.

**Figure 2.** Evolution of dialysis treatment graphics based on stakeholder input.





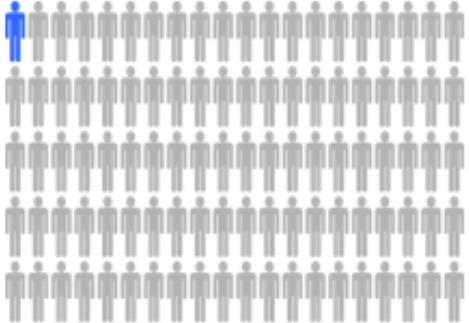
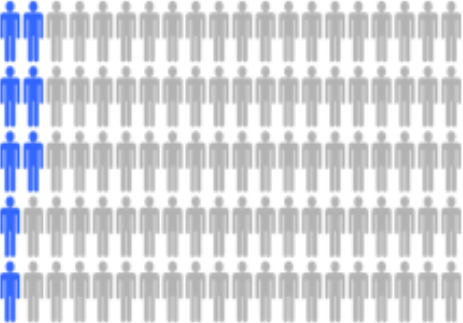


The survey graphics of in-center hemodialysis, the reference treatment, and wearable KRT devices, the alternative treatment, underwent iterative stakeholder-guided revisions. Changes to the in-center hemodialysis treatment graphic included: addition of a blood line and a healthcare professional (Panel B), followed by addition of a second blood line, elevation of the patients' feet, addition of machine detail, and change in color of the blood lines from gold to red to better resemble actual in-center bloodlines (Panel C). Changes to the wearable device graphics included: addition of a blood line, change in color of the people from black to gray, and removal of the vest-based graphic (Panel B), followed by change in color of the people from gray to tan, conversion of the backpack style from bulky to more compact, and change in color of the blood lines from red to gold to signify the potential discreteness of the device (Panel C).

**Figure 3.** Survey content overview



The final survey is a 54-item web-based instrument that includes 1) risk tradeoff questions designed to quantify the levels of potential risks of serious bleeding and serious infection that patients are willing to accept in exchange for the benefits of the wearable KRT devices; 2) modified time tradeoff questions to determine respondents' discount rate for time until wearable KRT devices are available; 3) comprehension questions to assess understanding of the presented information; and 4) health and background information questions. The full survey is available in the **Supplemental Materials**.

**Figure 4.** Example of a treatment choice question in the question series for eliciting maximum risk of serious bleeding patients would accept from a wearable KRT device in exchange for the benefits of the device relative to in-center hemodialysis.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious bleeding each year	 <1 out of 100 people (<1%)	 8 out of 100 people (8%)
Which option would you choose?		

To estimate the maximum acceptable risk for different devices, the survey includes 2 sets of 3 risk tradeoff questions, where respondents must choose between pairs of treatments: fixed reference treatment (in-center hemodialysis) and the alternative wearable RRT device as risk levels are varied. In the first set of risk tradeoff questions, the respondent must choose between pairs of treatment that differ in terms of the risk of serious bleeding (as shown in the figure). In the second set of risk tradeoff questions, the respondent must choose between pairs of treatment that differ in terms of the risk of serious infection (not shown). For each respondent, the survey generates a range in which the respondent's maximum acceptable risk for switching from the reference treatment to the alternative treatment. The data from the threshold technique portion of the survey will be analyzed using an interval regression model. The coefficients from this model will allow us to determine the average maximum acceptable risk for the sample and how that maximum acceptable risk varies by patient characteristics.

## **SUPPLEMENTAL MATERIALS**

*Flythe, J.E., et al. Development of a patient preference survey for wearable kidney replacement devices.*

### **Supplement Table of Contents**

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**Supplemental Table S1.** Stakeholders providing project support and guidance.

Name	Affiliation
<b><i>Steering Committee</i></b>	
Allen Chen, PhD	Food and Drug Administration, Center for Devices and Radiologic Health
Jennifer Flythe, MD, MPH (co-chair)*	University of North Carolina at Chapel Hill
Derek Forfang*	Patient Advisor
David Gebben, PhD*	Food and Drug Administration, Center for Devices and Radiologic Health
Gema Gonzalez	Food and Drug Administration, Center for Devices and Radiologic Health
Raymond Harris, MD*	Vanderbilt University
Frank Hurst, MD*	Food and Drug Administration, Center for Devices and Radiologic Health
Andrew Lo, PhD	Massachusetts Institute of Technology
Carolyn Neuland, PhD	Food and Drug Administration, Center for Devices and Radiologic Health
Anindita Saha	Food and Drug Administration, Center for Devices and Radiologic Health
Murray Sheldon, MD	Food and Drug Administration, Center for Devices and Radiologic Health
Grace Squillaci	Kidney Health Initiative
Michelle Tarver, MD, PhD (co-chair)	Food and Drug Administration, Center for Devices and Radiologic Health
Melissa West*	American Society of Nephrology
<b><i>Survey Development Workgroup</i></b>	
Kerri Cavanaugh, MD, MHS	Vanderbilt University
Jennifer Flythe, MD, MPH (chair)*	University of North Carolina at Chapel Hill
Derek Forfang*	Patient Advisor
Nieltje Gedney	Patient Advisor
Raymond Harris, MD*	Vanderbilt University
Frank Hurst, MD*	Food and Drug Administration, Center for Devices and Radiologic Health
David Gebben, PhD*	Patient Advisor
Carol Mansfield, PhD	RTI Health Solutions
Grace Squillaci, MBA	American Society of Nephrology
Katherine Treiman, PhD, MPH	RTI Health Solutions
Melissa West*	American Society of Nephrology
David White	Patient Advisor
Caroline Wilkie	Patient Advisor
Dallas Wood, PhD	RTI Health Solutions
Mark Unruh, MD, MS	University of New Mexico

\* Individuals who were members of both the project steering committee and survey development workgroup.

**Supplemental Table S2.** Environmental scan of KRT research and development activities.<sup>a</sup>

Device [Developer, Location]	Device type & description
Ambulatory Kidney to Improve Vitality (AKTIV) [Center for Dialysis Innovation, USA]	<u>HD portable/wearable</u> : miniaturized HD system
Automated Wearable Artificial Kidney (AWAK) [AWAK Technologies, Singapore]	<u>HD and PD wearable</u> : miniaturized HD and PD systems that use sorbent technology
MiniKid [Nanodialysis, Netherlands]	<u>HD portable/wearable</u> : miniaturized HD system that uses sorbent technology
PDeasy [Nanodialysis, Netherlands]	<u>PD portable/wearable</u> : miniaturized PD system that uses sorbent technology
Qidni TM Wearable Device [Kitchener, Canada]	<u>HD portable</u> : miniaturized HD system that uses sorbent technology
Rene Artificiale Portatile (RAP) [University of Padova and International Research Institute of Vicenza, Italy]	<u>UF portable/wearable</u> : miniaturized fluid removal system that is designed to be worn in a backpack or pulled on a trolley
Vicenza Wearable Artificial Kidney (ViWAK) [International Research Institute of Vicenza, Italy]	<u>PD wearable</u> : miniaturized PD system that uses sorbent technology
Wearable Artificial Kidney (WAK) [WAK Foundation, USA]	<u>HD wearable</u> : miniaturized HD system that uses sorbent technology
WEAKID [Universitair Medisch Centrum Utrecht and Nanodialysis, Netherlands]	<u>PD wearable</u> : miniaturized PD system that uses sorbent technology

<sup>a</sup> We conducted an environmental scan of recent research and development activities relevant to KRT to inform the device descriptions. Specifically, we searched PubMed for English language articles (search date: February 1, 2020) about new KRT products (i.e., stage of development, attributes, clinical trial data). We supplemented the PubMed search with publicly available information from the Kidney Innovation Accelerator (KidneyX) program and industry market reports.

Abbreviations: HD, hemodialysis; KRT, kidney replacement therapy; PD, peritoneal dialysis; UF, ultrafiltration.

**Supplemental Table S3.** Representative concept elicitation and pre-test interview guide questions.

<b>Concept Elicitation Interview Questions and Probes</b>
<p>Q. Had you ever heard anything about a wearable dialysis device before this discussion today?  PROBE: What have you heard about it?</p> <p>Q. <i>[Following provision of device descriptions]</i> Based on this information, what is your initial reaction to a wearable dialysis device?  PROBE: What questions do you have about these devices?</p> <p>Q. What do you think the potential benefits would be of using a wearable device?  PROBE: Which of these potential benefits would be most important to you personally?  PROBE: What are the reasons this/these would be important to you?  PROBE: What benefits might be important to others? Why?</p> <p>Q. What do you think the potential harms or downsides would be of using a wearable device?  PROBE: Which of these potential downsides would be of most concern to you personally?  PROBE: What are the reasons this/these would be of most concern to you?  PROBE: What concerns do you think others might have? Why?</p> <p>Q. Overall, how would you compare a wearable dialysis device to your current type of dialysis?  PROBE: What are the advantages and disadvantages compared to your current type of dialysis?</p> <p>Q. If a wearable dialysis device becomes available, how interested would you be in using it?  PROBE: What are reasons you would/or would not be interested in using a wearable device?</p> <p>Q. What additional information would you want about a wearable device?  PROBE: How would this information affect your decision about whether or not to use a wearable device?</p> <p>Q. What additional worries do you have about wearable devices?</p>
<b>Pre-Test Interview Questions and Probes</b>
<p><i>[Interviewer used a “think-aloud” approach in which participants read the survey aloud and shared what they were thinking as they read information, interpreted instructions and questions, and selected their responses.]</i></p>
<p><b>Comprehension by participants</b></p>
<p>Q. To what extent does the information you read in this section help you understand how wearable devices work?  PROBE: How easy or hard is it to understand this information?</p> <p>Q. In your own words, describe what you would have to do if you chose to use a wearable device.</p> <p>Q. What would make the information more clear?  PROBE: Are there any words or phrases that are not familiar to you?</p> <p>Q. What do you think this picture is trying to show?  PROBE: Is there anything unclear or confusing about this picture?</p>
<p><b>Effective communication of benefit, harm, risk, uncertainty</b></p>
<p>Q. Is there anything else you would want to know about a wearable device that is not described here?</p> <p>Q. What is your understanding of how serious bleeding/serious infection can occur?</p> <p>Q. In your own words, how would you describe the risk of serious infection/serious bleeding? How is this risk different for in-center vs. wearable dialysis?</p>
<p><b>Patient-centeredness</b></p>
<p>Q. After reading this section, what is your reaction to the idea of a wearable device?</p> <p>Q. (Risk and time tradeoff series) What did you think about in choosing this answer?  PROBE: Which of these factors was most important to you?</p>
<p><b>Minimal cognitive bias</b> (Questions reference the survey table comparing in-center hemodialysis and wearable)</p>
<p>Q. Is there anything more that you would want to know after reading this table ?</p> <p>Q. What would make this table more useful or helpful to you?</p> <p>Q. After reading the information in this table, how interested would you be in using a wearable device?</p> <p>Q. What information did you consider when thinking about your interest in a wearable device?</p>

Abbreviations: Q, question.

**Supplemental Table S4.** Survey risk levels and supporting evidence.

Risk and device	Risk levels (per year)	Approach/ Supporting evidence
<b>Serious bleeding</b>		
<b>In-center hemodialysis</b>	<1 out of 100	<ul style="list-style-type: none"> <li>• <b>Primary data source:</b> U.S. Veterans Affairs.<sup>1</sup> <ul style="list-style-type: none"> <li>◦ <u>Data:</u> 2.5 million HD treatments at VA facilities from 2002 to 2008</li> <li>◦ <u>Finding:</u> 78 serious safety reports; of those, 40 were serious bleeds and all involved dislodgement of the venous needle or disconnection of the venous blood line at the dialysis catheter attachment</li> <li>◦ <u>Finding:</u> Risk of serious bleeding = 40 serious bleeds/2.5 million treatments → 0.000016 per treatment</li> </ul> </li> <li>• <b>Assumptions, Calculations, and Additional Considerations:</b> <ul style="list-style-type: none"> <li>◦ Calculated risk of serious bleeding per treatment and then per year</li> <li>◦ Hypothesized that the calculated risk (0.25 per year) was an under-estimation since it does not account for serious bleeding occurring outside of the dialysis clinics.</li> <li>◦ Specified the risk as <b>&lt;1 out of 100 per year</b>.</li> </ul> </li> </ul>
<b>Wearable KRT device (HD or PD)</b>	8 out of 100	<ul style="list-style-type: none"> <li>• We used home HD literature to estimate the bleeding risk levels for wearable devices, adjusting the risk based on the number of hours of therapy. This approach anchors the risk of bleeding to pump time.</li> <li>• <b>Primary data source:</b> Wong. <i>Am J Kid Dis</i>, 2014.<sup>2</sup> <ul style="list-style-type: none"> <li>◦ <u>Data:</u> 2 home HD programs in Canada (2001-2012); 190 patients (500 patient-years of treatments)</li> <li>◦ <u>Finding:</u> 1 death and 6 potentially fatal events (6 of the 7 events involved serious blood loss) for a crude rate of 0.06 events/1,000 treatments; on average, patients in the study were treated 27 hours/week.</li> </ul> </li> <li>• <b>Assumptions, Calculations, and Additional Considerations:</b> <ul style="list-style-type: none"> <li>◦ Based on input from developers, assumed the device would be worn 23 hours/day (161 hours/week)</li> <li>◦ Calculated a comparable risk for wearable devices based on pump time and then per year</li> <li>◦ Specified the risk as <b>8 out of 100 per year</b></li> </ul> </li> </ul>
<b>Serious infection</b>		
<b>In-center hemodialysis</b>	6 out of 100	<ul style="list-style-type: none"> <li>• We considered the range of serious infection risks based on vascular access type (catheter vs. AVF vs. AVG)</li> <li>• <b>Primary data source:</b> Brown. <i>Clin J Am Soc Nephrol</i>, 2018.<sup>3</sup> <ul style="list-style-type: none"> <li>◦ <u>Data:</u> CROWNWeb and National Healthcare Safety Network data from 179 Medicare facilities in New England (2015-2016); on average, included 12,693 patients per month</li> <li>◦ <u>Finding:</u> Monthly BSI rate 0.52 per 100 patient-months (any access type); BSI rate for catheters= 2.15 per 100 patient-months and BSI rate for non-catheters= 0.23 per 100 patient-months</li> </ul> </li> <li>• <b>Assumptions, Calculations, and Additional Considerations:</b> <ul style="list-style-type: none"> <li>◦ Calculated risk of serious infection per year</li> <li>◦ Specified the risk as <b>6 out of 100 per year</b></li> </ul> </li> </ul>
<b>Wearable KRT device (HD or PD)</b>	31 out of 100	<ul style="list-style-type: none"> <li>• We considered in-center HD with a catheter infection risk and peritonitis risk to estimate the infection risk level of the wearable KRT device, and adjusted the risk based on the number of times the catheter would be accessed. This approach anchors the risk to catheter access (and catheter duration).</li> <li>• <b>Primary data source (1) for in-center HD with a catheter:</b> Nguyen. <i>Clin J Am Soc Nephrol</i>, 2017.<sup>4</sup> <ul style="list-style-type: none"> <li>◦ <u>Data:</u> 6,005 outpatient HD facilities reporting data to the National Healthcare Safety Network in 2014</li> <li>◦ <u>Finding:</u> rate of BSI per 100 patient-months= 0.64 (0.26 for AVF, 0.39 for AVF, and 2.16 for catheter)</li> </ul> </li> <li>• <b>Primary data source (2) for in-center HD with a catheter:</b> Brown. <i>Clin J Am Soc Nephrol</i>, 2018.<sup>3</sup></li> </ul>

		<ul style="list-style-type: none"> <li>○ <u>Data</u>: CROWNWeb and National Healthcare Safety Network data from 179 Medicare facilities in New England (2015-2016); on average, included 12,693 patients per month</li> <li>○ <u>Finding</u>: Monthly bloodstream infection (BSI) rate 0.52 per 100 patient-months (any access type); BSI rate for catheters= 2.15 per 100 patient-months</li> <li>● <b>Primary data source for PD (peritonitis)</b>: Perl. <i>Am J Kid Dis</i>, 2020.<sup>5</sup> <ul style="list-style-type: none"> <li>○ <u>Data</u>: 7,051 adult PD patients in 209 clinics across 7 countries (Dialysis Outcomes and Practice Patterns Study)</li> <li>○ <u>Finding</u>: crude rate of peritonitis= 28 per 100 patient-years</li> </ul> </li> <li>● <b>Assumptions, Calculations, and Additional Considerations</b>: <ul style="list-style-type: none"> <li>○ Hypothesized that the calculated risk for HD wearable KRT devices (26 per 100 patient-years) was an under-estimation since the wearable KRT catheter would be accessed more frequently than a catheter for in-center HD.</li> <li>○ Adjusted for more frequent hub access</li> <li>○ Calculated risk of serious infection per year for HD wearable KRT devices</li> <li>○ Specified the risk as 34 out of 100 per year for HD wearable KRT devices</li> <li>○ Calculated risk of serious infection per year for PD wearable KRT devices</li> <li>○ Specified the risk as 28 out of 100 per year for PD wearable KRT devices</li> <li>○ Averaged the HD and PD risks to calculate the final risk of 31 out of 100 per year</li> </ul> </li> </ul>
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Abbreviations: AVF, arteriovenous fistula; AVG, arteriovenous graft; BSI, blood stream infection; HD, hemodialysis; PD, peritoneal dialysis; tmt, treatment.

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# **Patient Survey:**

## **Wearable Dialysis Device**

### **Welcome**

The purpose of this survey is to understand what people with kidney failure think about a wearable dialysis device, a potential new type of treatment. The Kidney Health Initiative is conducting the survey with RTI International, a nonprofit research organization. This survey is for people currently using any type of dialysis.

**Thank you** for taking the time to complete the survey! Your answers will help companies developing wearable dialysis devices understand what is important to patients. The survey results will also be helpful to the U.S. Food and Drug Administration (FDA), which approves medical devices.

### About the Kidney Health Initiative

The Kidney Health Initiative is a partnership between the American Society of Nephrology, the FDA, patients and caregivers, and clinicians and companies that develop new treatments. See [Kidney Health Initiative](#) for more information. The FDA provided funding to conduct this survey.

### **Le damos la bienvenida**

El objetivo de esta encuesta es conocer la opinión de las personas con insuficiencia renal sobre una máquina portátil de diálisis, un posible nuevo tipo de tratamiento. La Iniciativa de Salud Renal (o Kidney Health Initiative) está realizando la encuesta junto a RTI International, una organización sin fines de lucro que realiza estudios de investigación. Esta encuesta está dirigida a las personas que, en este momento, utilizan cualquier tipo de diálisis.

**¡Gracias** por tomarse el tiempo para completar la encuesta! Sus respuestas ayudarán a las compañías que fabrican máquinas portátiles de diálisis a entender lo que es importante para los pacientes. Los resultados de la encuesta también serán útiles para la Administración de Alimentos y Medicamentos de Estados Unidos (FDA, por sus siglas en inglés), que aprueba los dispositivos médicos.

### Información sobre la Iniciativa de Salud Renal

La Iniciativa de Salud Renal es una asociación entre la Sociedad Estadounidense de Nefrología (ASN, por sus siglas en inglés), la FDA, los pacientes y cuidadores, y los médicos y compañías que desarrollan nuevos tratamientos. Para obtener más información, consulte the Kidney Health Initiative (la [Iniciativa de Salud Renal](#)). La FDA ofreció fondos para realizar esta encuesta.

## 1. Screener Questions

Please answer the following questions to confirm that you are eligible to participate in this survey.

## 1. Preguntas de selección de participantes

Responda las siguientes preguntas para confirmar que reúne los requisitos para participar en esta encuesta.

S1. How old are you? **[Screen out if < 22]**

\_\_\_\_\_ (years)

¿Cuántos años tiene? **[Screen out if < 22]**

\_\_\_\_\_ (años)

S2. Do you live in the United States?

Yes

No [Screen out]

¿Vive en los Estados Unidos?

Sí

No [Screen out]

S3. In which state do you currently live?

\_\_\_\_\_

En este momento, ¿en qué estado vive?

\_\_\_\_\_

S4. Are you currently on dialysis for kidney failure?

Yes

No [Screen out]

En este momento, ¿recibe diálisis por insuficiencia renal?

Sí

No [Screen out]

S5. How long have you been on dialysis for kidney failure?

☐ Less than 3 months [Screen out]

☐ 3 months to 1 year

☐ More than 1 year

¿Hace cuánto que recibe diálisis por insuficiencia renal?

☐ Menos de 3 meses [Screen out]

☐ 3 meses a 1 año

☐ Más de 1 año

S6. Are you currently participating in a clinical trial for a dialysis machine?



☐ Yes [Screen out]

☐ No

En este momento, ¿participa en un estudio clínico para una máquina de diálisis?

☐ Sí [Screen out]

☐ No

S7. Are you

Female

Male

Other gender identity

Prefer not to answer

¿Es usted...?

Mujer

Hombre

Otra identidad de género

Prefiere no decirlo

S8. Are you Hispanic or Latino?

Yes

No

¿Es usted hispano(a) o latino(a)?

Sí

No

S9. How do you identify yourself?

*(Select all that apply)*

White

Black or African American

Asian

Native Hawaiian or Other Pacific Islander

Some other race [specify]

¿Cómo se identifica a usted mismo(a)?

*(Seleccione todas las opciones que correspondan)*

Blanco(a)

Negro(a) o afroamericano(a)

Asiático(a)

Nativo(a) de Hawái u otro(a) isleño(a) del Pacífico

Alguna otra raza [especifique]

S10. What is the highest level of school you have completed or the highest degree you have received?

Less than high school

High school or equivalent (or GED)

Some college but no degree

Associates degree in college or technical school degree

4-year college degree

Advanced or postgraduate degree

¿Cuál es el nivel escolar más alto que completó o el título más alto que recibió?

No terminó la escuela secundaria

Se graduó de la escuela secundaria o equivalente (diploma de educación general básica [GED])

No terminó la universidad

Se graduó con título de asociado en la universidad o título de escuela técnica

Título de 4 años de universidad

Se graduó con título superior o de posgrado

## Consent to Participate

Please read the following information carefully and select whether you agree to participate or not. [Please click [here](#) to print a copy of this consent form for your records.]

### **What does this study involve?**

This survey will take approximately 30-45 minutes to complete.

### **What information do I need to share to be in this study?**

You do not have to share any information that identifies who you are to participate.

### **What rights do I have as a study participant?**

Taking part in this study is up to you.

You may decide to stop at any time, and you do not have to give a reason for stopping.

### **What are the benefits to participating?**

There is no guarantee of a direct benefit to you for being in this study. However, the information you provide will help Kidney Health Initiative better understand what matters most to patients about treatment options for kidney failure.

**What are the risks to participating?**

There are minimal risks to participating in the survey. However, some respondents may feel uncomfortable answering questions about their health or dialysis treatment.

**Will my responses be shared with others?**

Your responses will be kept private to the extent allowable by law and will be used only for this research.

Many precautions have been taken to protect your information. The findings from this study will be reported in summary form, so that the participants cannot be identified.

**Will I receive an incentive for completing the survey?**

- As a thank you for your time to complete the survey, we will send a \$35 gift card. You may complete the survey one time only and receive one gift card. At the end of the survey you will be asked to provide your contact information so that we can send the gift card.. To protect your privacy, your contact information will be kept separate from your answers on the survey.

**Persons to Contact:**

xxxxxx

**Instructions for Completing the Survey**

This survey is not compatible with mobile phones, please respond to this survey on your personal computer or tablet.

Please complete the survey in one sitting. Do not close out of the survey once you have started. If you close out you will not be able to return to the survey. The survey will close out by itself if you are not active (move to a new page) after 30 minutes.

To protect your privacy, please be sure other people cannot see your open survey.

You can skip some questions in the survey if you are not comfortable answering them. However, other questions are required to continue with the survey. If you are not comfortable answering any of the required questions, you may stop at any time.

## Consentimiento para participar

Lea atentamente la siguiente información y seleccione si está de acuerdo en participar o no. [Haga clic aquí para imprimir una copia de este formulario de consentimiento para sus archivos].

### ¿En qué consiste este estudio?

Le tomará alrededor de 30 a 45 minutos completar esta encuesta.

### ¿Qué información debo compartir para participar en este estudio?

No tiene que compartir ninguna información que lo/la identifique para participar.

### ¿Qué derechos tengo como participante del estudio?

Participar en este estudio depende de usted.

Puede decidir detenerse en cualquier momento y no tiene que dar una razón para hacerlo.

### ¿Cuáles son los beneficios de participar?

No se garantiza un beneficio directo para usted por participar en este estudio. Sin embargo, la información que proporcione ayudará a la Iniciativa de Salud Renal a comprender mejor lo que es más importante para los pacientes sobre las opciones de tratamiento de la insuficiencia renal.

### ¿Cuáles son los riesgos de participar?

Participar en la encuesta tiene un riesgo mínimo. Sin embargo, algunos participantes pueden sentirse incómodos al responder preguntas sobre su salud o tratamiento de diálisis.

### ¿Se compartirán mis respuestas con otras personas?

Se conservará la privacidad de sus respuestas en la medida en que lo permita la ley y se utilizarán únicamente para esta investigación científica.

Se tomaron muchas precauciones para proteger su información. Los resultados de este estudio se presentarán de forma resumida, de modo que no se pueda identificar a los participantes.

### ¿Recibiré un incentivo para completar la encuesta?

- Como agradecimiento por su tiempo para completar la encuesta, le enviaremos una tarjeta de regalo de \$35 dólares. Puede completar la encuesta una sola vez

y recibir una tarjeta de regalo. Al final de la encuesta, se le pedirá que proporcione su información de contacto para que podamos enviar la tarjeta de regalo. Para proteger su privacidad, su información de contacto se mantendrá separada de sus respuestas en la encuesta.

**Personas de contacto:**

xxxxx

**Instrucciones para completar la encuesta**

Esta encuesta no es compatible con teléfonos móviles, por favor responda a esta encuesta en su computadora personal o tableta.

Por favor, complete la encuesta en una sola sesión. No cierre la encuesta una vez que haya comenzado. Si la cierra, no podrá volver a la encuesta. La encuesta se cerrará por si misma por inactividad (si no pasa de una página a otra) después de 30 minutos.

Para proteger su privacidad, asegúrese de que otras personas no puedan ver su encuesta mientras la completa.

Puede omitir algunas preguntas de la encuesta si no se siente cómodo(a) contestándolas. Sin embargo, será necesario responder otras preguntas para continuar con la encuesta. Si no se siente cómodo(a) respondiendo a cualquiera de las preguntas requeridas, puede detenerse en cualquier momento.

## **2. In-Center Hemodialysis and Wearable Dialysis Devices**

In this survey, we will describe two ways to get dialysis treatment and some of the differences between them.

The first way is treatment with in-center hemodialysis

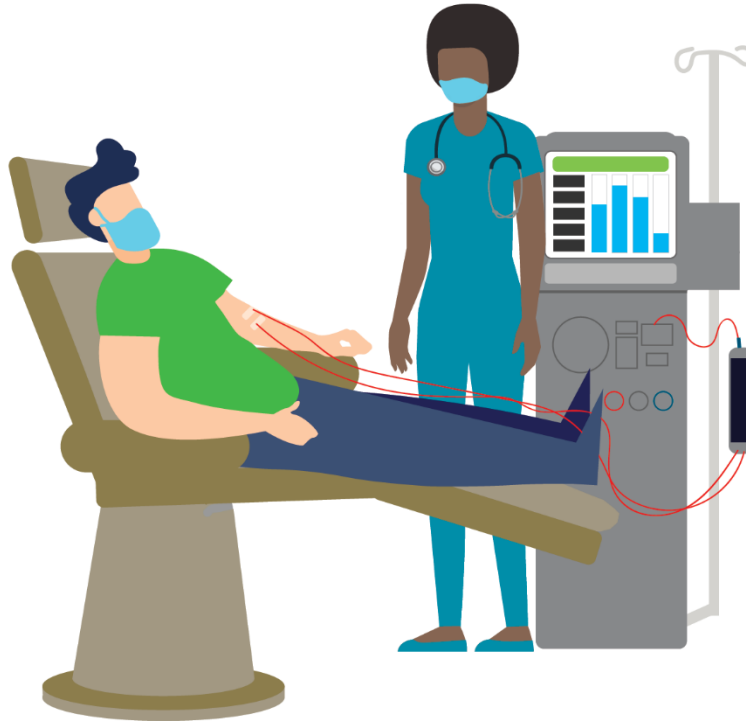
The second way is treatment with a device you wear that provides dialysis, either as hemodialysis or peritoneal dialysis

Below we describe them in more detail.

Whether you get in-center hemodialysis or use a wearable dialysis device, you would be cared for by a kidney doctor who is familiar with the treatment and can help you manage

the treatment. Also, please assume that the wearable dialysis device would be covered and reimbursed by Medicare and other insurance in the same way as in-center hemodialysis.

## 2.1 In-Center Dialysis Description



In-center hemodialysis (see picture above) is the most common form of dialysis. This treatment takes place at a dialysis center. At the dialysis center, trained staff connect the dialysis machine to your bloodstream, watch your vital signs during treatment, and clean the equipment after each use.

Here are the answers to some frequently asked questions about in-center dialysis.

### **How does in-center hemodialysis work?**

To receive this treatment, you need to visit a dialysis center 3 times each week. Each visit lasts 3–4 hours.

During each treatment, a hemodialysis machine is connected to your bloodstream using a dialysis access, either a fistula, a graft, or a catheter. First, the hemodialysis machine pumps blood from your body into the machine. The machine then cleans your blood, removes extra fluid, and then sends the clean blood back to your body.

Since you don't get in-center hemodialysis every day, your body may need some medications to stay healthy. You may also have to change some of what you eat and drink. You may notice some symptoms. These are discussed later in the survey.

## **2. Hemodiálisis en el centro y máquinas portátiles de diálisis**

En esta encuesta, describiremos dos formas de recibir tratamiento de diálisis y algunas de las diferencias entre ellas.

La primera forma es el tratamiento con hemodiálisis en el centro.

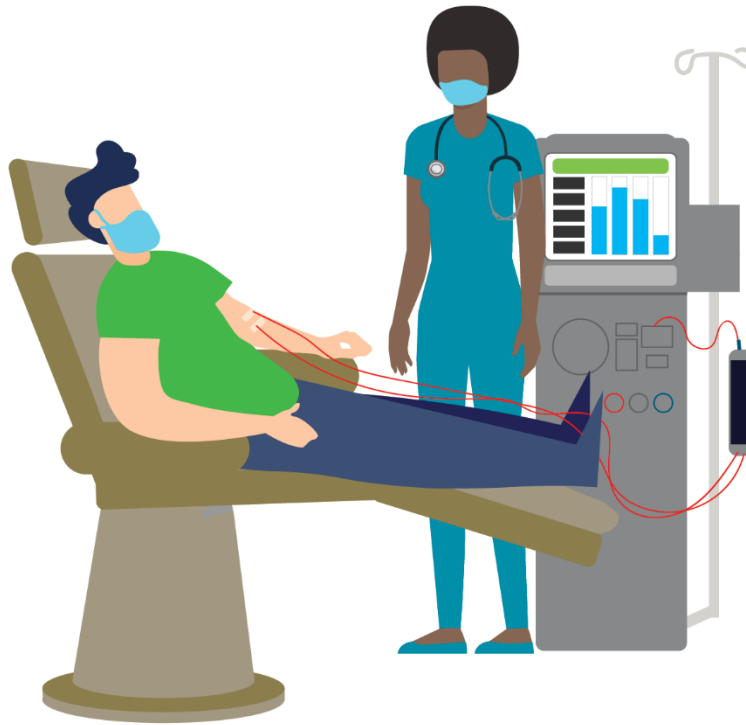
La segunda forma es el tratamiento con una máquina que se lleva puesto y que proporciona diálisis, ya sea como hemodiálisis o diálisis peritoneal.

A continuación, los describimos con más detalle.

Ya sea que reciba hemodiálisis en el centro o si utiliza una máquina portátil de diálisis, lo atenderá un médico especialista en riñón que esté familiarizado con el tratamiento y pueda ayudarlo a gestionarlo. Además, suponga que Medicare y otros seguros cubren y reembolsan la máquina portátil de diálisis de la misma manera que la hemodiálisis en el centro.



## 2.1 Descripción de la diálisis en el centro



La hemodiálisis en el centro (vea la imagen de arriba) es la forma más común de diálisis. Este tratamiento se realiza en un centro de diálisis. En el centro de diálisis, personal capacitado conecta la máquina de diálisis a sus vasos sanguíneos, observa sus signos vitales durante el tratamiento y limpia el equipo después de cada uso.

A continuación, le presentamos las respuestas a algunas preguntas frecuentes sobre la diálisis en el centro.

### **¿Cómo funciona la hemodiálisis en el centro?**

Para recibir este tratamiento, es necesario acudir a un centro de diálisis 3 veces por semana. Cada visita dura entre 3 a 4 horas.

Durante cada tratamiento, una máquina de hemodiálisis se conecta a los vasos sanguíneos mediante un acceso de diálisis, ya sea una fístula, un injerto o un catéter. Primero, la máquina de hemodiálisis bombea la sangre del cuerpo hacia ella. Luego, la máquina limpia la sangre, elimina el líquido sobrante y devuelve la sangre limpia al cuerpo.

Dado que no recibe hemodiálisis en el centro todos los días, el cuerpo puede necesitar algunos medicamentos para mantenerse sano. Es posible que también tenga que cambiar algo de lo que come y bebe. Puede presentar algunos síntomas. Estos aspectos se analizan más adelante en la encuesta.

Have you ever received in-center hemodialysis?

Yes

No

¿Recibió alguna vez hemodiálisis en el centro?

Sí

No

Have you ever received Home hemodialysis?

Yes

No

¿Recibió alguna vez hemodiálisis en el hogar?

Sí

No

Have you ever received Peritoneal Dialysis?

Yes

No

¿Recibió alguna vez diálisis peritoneal?

Sí

No

Have you ever had a kidney transplant?

Yes

No

¿Recibió alguna vez un trasplante de riñón?

Sí

No

Which type of dialysis are you currently receiving?

Home hemodialysis

In-center hemodialysis (at a dialysis center)

Peritoneal Dialysis

En este momento, ¿qué tipo de diálisis recibe?

Hemodiálisis en el hogar

Hemodiálisis en el centro (centro de diálisis)

Diálisis peritoneal

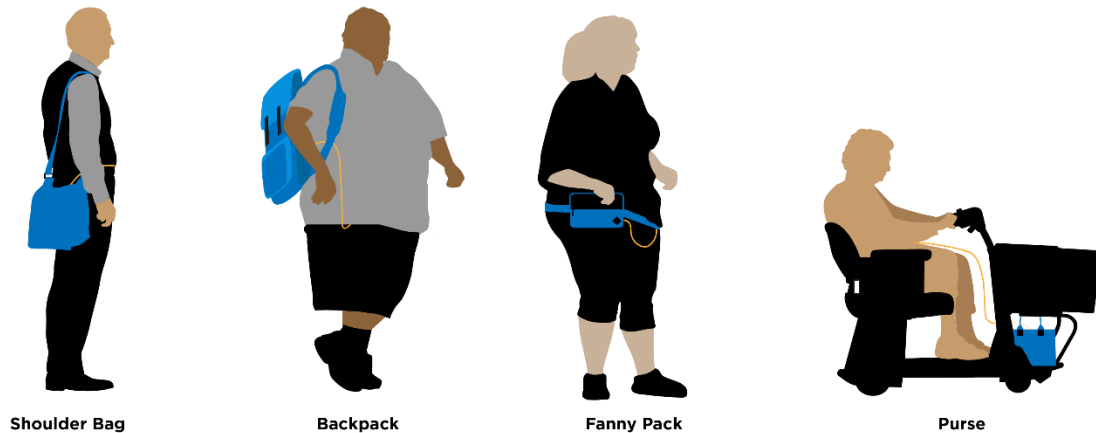
In what year did you start using your current dialysis type?

\_\_\_\_\_

¿En qué año comenzó a utilizar su tipo de diálisis actual?

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## 2.2 Wearable Dialysis Device Description



Wearable dialysis devices may be alternatives to in-center hemodialysis. This information describes wearable dialysis devices in general. Different devices may have somewhat different features and can be used for hemodialysis or peritoneal dialysis.

These devices hold everything you need for a dialysis treatment, including all the parts needed to clean your blood and remove and store extra fluid. Wearable dialysis devices also have safety monitors and a battery.

Wearable dialysis devices are worn on the body every day most of the time both day and night. Wearable dialysis devices clean your blood almost continuously. This is how wearable dialysis devices are similar to functioning kidneys, which continuously clean your blood.

As a result, you may need fewer medications and changes to what you eat and drink. You may also notice fewer symptoms with a wearable dialysis device compared to in-center hemodialysis. These are discussed later in the survey.

Here are the answers to some frequently asked questions about wearable dialysis devices.

### **How do wearable dialysis devices work?**

There are two types of wearable dialysis devices. Each type of device works a little differently.

1. **Hemodialysis wearable devices** are connected to your bloodstream through a flexible tube, called a catheter. First, the device pumps blood from your body into

the device. The device then cleans your blood a little at a time, removes extra fluid, stores the waste fluid in the device, and then sends the clean blood back to your body. About 3 to 4 times a day, you would need to dump out the fluid that the device has removed from your blood.

2. **Peritoneal dialysis (PD) wearable devices** work by using your own peritoneum—which is a membrane in your belly—to filter waste and remove fluid. Peritoneal dialysis is performed through a flexible tube called a catheter that is inserted into your belly. The fluid flows into the belly and stays there a little while—usually 4 to 6 hours—and is then drained out. About 3 to 4 times a day, you would need to dump out the fluid that the device has removed from your belly.

With both types of wearable dialysis devices, a part of the catheter stays outside the body and under your clothes as in the pictures above. This part of the catheter attaches to tubes that connect to the wearable dialysis device.

**How do I wear the device?** The device can fit in a bag that you carry, like a backpack, shoulder bag, fanny pack, or similar bag. See the pictures above.

**How much does the device weigh?** 5 to 10 pounds

**How often would I need to wear the device?** You would wear this device every day, most of the time, both day and night.

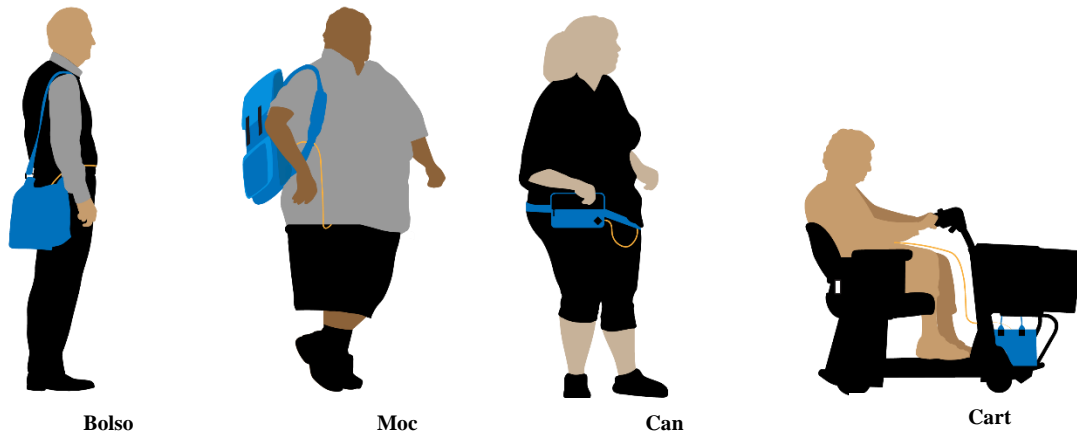
**Can I get the device wet?** It would depend on which device you have. If the device cannot get wet, you could disconnect the device for short periods of time before taking a shower, swimming, or other activities where you may get wet.

**What would I need to do to take care of the device?** Before you begin using a wearable dialysis device, you would be trained on how to use it and how to take care of it (for example, how to clean it). There would be someone you could call at any time if you need help (for example, a 24-hour help line).

**What would happen if the device stopped working?** The device would alert you that it is no longer working. You would not be in immediate danger, and you would not have to go to an emergency room. But, you would need to contact your healthcare provider as soon as possible. If the device could not be fixed quickly, you would need to get dialysis treatment at a center while you waited for your device to be fixed.

**Would I still need to visit a dialysis center on a regular basis?** Yes, you would need to visit a dialysis center about once a month for a device and medical check-up.

## 2.2 Descripción de la máquina portátil de diálisis



Las máquinas portátiles de diálisis pueden ser una alternativa a la hemodiálisis en el centro. En esta información se describen las máquinas portátiles de diálisis en general. Las distintas máquinas pueden tener características algo diferentes y pueden utilizarse para la hemodiálisis o la diálisis peritoneal.

Estas máquinas contienen todo lo necesario para un tratamiento de diálisis, incluidas todas las piezas necesarias para limpiar la sangre y eliminar y almacenar el líquido sobrante. Las máquinas portátiles de diálisis también tienen monitores de seguridad y una batería.

Las máquinas portátiles de diálisis se llevan en el cuerpo la mayor parte del tiempo, tanto de día como de noche. Estos limpian la sangre casi de forma continua. Así, las máquinas portátiles de diálisis son similares a los riñones en funcionamiento, que limpian la sangre de forma continua.

Como resultado, puede necesitar menos medicamentos y cambios en lo que come y bebe. También puede presentar menos síntomas con una máquina portátil de diálisis en comparación con la hemodiálisis en el centro. Estos aspectos se analizan más adelante en la encuesta.

A continuación, le presentamos las respuestas a algunas preguntas frecuentes sobre la máquina portátil de diálisis.

### ¿Cómo funciona esta máquina?

Hay dos tipos de máquinas portátiles de diálisis. Cada uno funciona algo diferente.

3. Las máquinas portátiles **de hemodiálisis** se conectan a sus vasos sanguíneos a través de un tubo flexible, llamado catéter. Primero, la máquina bombea sangre del cuerpo hacia él. Luego, la máquina limpia la sangre poco a poco, elimina el líquido sobrante, almacena el líquido de desecho en la máquina y devuelve la sangre limpia al cuerpo. Alrededor de 3 o 4 veces al día, tendrá que tirar el líquido que la máquina eliminó de la sangre.
4. Las máquinas portátiles **de diálisis peritoneal (DP)** funcionan con su propio peritoneo, que es una membrana del vientre, para filtrar los desechos y eliminar el líquido. La diálisis peritoneal se realiza a través de un tubo flexible, llamado catéter, que se introduce en el vientre. El líquido fluye hacia el vientre y permanece allí un tiempo, generalmente de 4 a 6 horas, y luego se drena. Alrededor de 3 o 4 veces al día, tendrá que tirar el líquido que la máquina eliminó del vientre.

En ambos tipos de máquinas portátiles de diálisis, una parte del catéter permanece fuera del cuerpo y bajo la ropa, como en las imágenes de arriba. Esta parte del catéter se une a los tubos que se conectan a la máquina portátil de diálisis.

¿**Cómo debo llevar la máquina?** La máquina puede caber en una bolsa, como una mochila, un bolso bandolera, una cangurera/riñonera o una bolsa similar. Vea las fotos de arriba.

¿**Cuánto pesa la máquina?** De 5 a 10 libras (2,25 kg a 4,50 kg).

¿**Con qué frecuencia debo llevar la máquina?** Deberá utilizar esta máquina todos los días, la mayor parte del tiempo, tanto de día como de noche.

¿**Puedo mojar la máquina?** Depende de la máquina que tenga. Si la máquina no puede mojarse, puede desconectarlo durante breves períodos antes de ducharse, nadar o realizar otras actividades en las que pueda mojarse.

¿**Qué debo hacer para cuidar la máquina?** Antes de empezar a utilizar una máquina portátil de diálisis, se le explicará cómo utilizarlo y cuidarlo (por



ejemplo, cómo limpiarlo). Habrá alguien a quien podrá llamar en cualquier momento si necesita ayuda (por ejemplo, una línea de ayuda de 24 horas).

**¿Qué pasaría si la máquina deja de funcionar?** La máquina le avisará que ya no funciona. No tendrá que exponerse al peligro inmediato ni tendrá que ir a urgencias. Sin embargo, deberá comunicarse con el proveedor de atención médica lo antes posible. Si la máquina no pudiera arreglarse con rapidez, tendrá que recibir tratamiento de diálisis en un centro mientras espera que le arreglen la máquina.

**¿Tendré que seguir acudiendo a un centro de diálisis con regularidad?** Sí, tendrá que acudir a un centro de diálisis aproximadamente una vez al mes para que le revisen la máquina y lo(a) revisen a usted.

Had you heard of a wearable dialysis device before taking this survey?

Yes

No

¿Había oído hablar de una máquina portátil de diálisis antes de realizar esta encuesta?

Sí

No

[If Q7=Yes] Where did you first hear about wearable dialysis devices?

*(Check all that apply)*

Doctor or other health professional

Another patient

Family member or friend

Patient support organization or group (Please specify)

Media source. For example, newspaper, TV, etc.

Social media source. For example, Facebook, Twitter, etc.

Other [specify]

[Si la Q7 = Sí] ¿Dónde oyó hablar por primera vez de las máquinas portátiles de diálisis?

*(Marque todas las opciones que correspondan)*

Médico u otro profesional de la salud

Otro paciente

Familiares o amigos

Organización o grupo de apoyo al paciente (especifique)

Medios de comunicación. Por ejemplo, el periódico, la televisión, etc.

Redes sociales. Por ejemplo, Facebook, Twitter, etc.

Otro [especifique]

The table below lists some of the big differences between getting in-center hemodialysis and using a wearable dialysis device.

Feature of dialysis	In-Center Hemodialysis	Wearable Dialysis Device
How often will I need to visit a dialysis center?	3 times each week for 3 to 4 hours per visit. Purpose of visit: get dialysis treatment.	1 time per month Purpose of visit: healthcare staff will conduct a device and medical check-up.
Will healthcare staff be present to monitor me during treatment?	YES Trained staff watch your vital signs and the machine during treatment	NO Help would always be available (for example, a 24-hour support line).
Can I move during treatment?	NO You must remain seated while attached to the dialysis machine in the dialysis center.	YES You would go about your normal activities while getting dialysis through the device. You may have more freedom, such as going to work, going to school, traveling and participating in other activities.
Will I need to take care of the device?	NO	YES You would be responsible for taking care of the device, for example cleaning it regularly. You would need to be careful not to damage the device. You would receive training and help would be available (for example, a 24-hour support line).
Will I need to make changes to my diet?	YES When you receive this treatment, you will need to:	YES

Feature of dialysis	In-Center Hemodialysis	Wearable Dialysis Device
	Avoid certain types of foods (like foods that contain a lot of potassium or phosphate-) Limit how much fluid you have in a day	However, you will need to make fewer dietary changes compared to in-center dialysis. You may be able to: Eat more types of foods (like foods that contain a lot of potassium-or phosphate-) Drink more fluids
Will I need to take medications?	YES When you receive this treatment, you will need to take medications (like phosphate binders).	YES However, compared to in-center dialysis, you may need to take fewer medications (like phosphate binders).
Will I have symptoms as a result of this treatment?	YES You may have: muscle cramping shortness of breath fainting or dizziness	YES However, compared to in-center dialysis, you may have fewer symptoms because your blood is cleaned almost continuously.  You may: have less muscle cramping have less shortness of breath have less fainting or dizziness feel less tired or washed out

Before we continue, we want to ask you a few questions to make sure you understood the differences between these treatments.

La siguiente tabla muestra algunas de las diferencias más importantes entre recibir hemodiálisis en el centro y utilizar una máquina portátil de diálisis.

Características de la diálisis	Hemodiálisis en el centro	Máquina portátil de diálisis
¿Con qué frecuencia tendré que acudir a un centro de diálisis?	3 veces por semana durante 3 o 4 horas por consulta Objetivo de la consulta: recibir tratamiento de diálisis.	1 vez por mes Objetivo de la consulta: el personal de atención médica realizará una revisión médica y de la máquina.
¿Estará presente el personal de atención para controlarme durante el tratamiento?	SÍ El personal capacitado observa sus signos vitales y la máquina durante el tratamiento.	NO Siempre habrá ayuda disponible (por ejemplo, una línea de apoyo de 24 horas).
¿Puedo desplazarme durante el tratamiento?	NO Debe permanecer sentado mientras esté conectado a la máquina de diálisis en el centro de diálisis.	SÍ Seguirá con sus actividades normales mientras recibe la diálisis a través de la máquina. Puede tener más libertad como ir a trabajar, ir a la escuela, viajar y participar en otras actividades.
¿Tendré que ocuparme de la máquina?	NO	SÍ Tendrá que cuidar de la máquina, por ejemplo, de limpiarla con regularidad. Hay que tener cuidado de no dañar la máquina. Se le capacitará y recibirá ayuda cuando la necesite (por ejemplo, mediante una línea de apoyo de 24 horas).
¿Tendré que hacer cambios en mi alimentación?	SÍ Cuando reciba este tratamiento, tendrá que cumplir con lo siguiente: Evitar determinados tipos de alimentos (como los que contienen mucho potasio o fosfato). Limitar la cantidad de líquido que toma al día.	SÍ Sin embargo, tendrá que hacer menos cambios en la alimentación en comparación con la diálisis en el centro. Puede tener que realizar lo siguiente: Consumir muchos tipos de alimentos (como los que contienen mucho potasio o fosfato). Beber más líquidos.
¿Tendré que tomar medicamentos?	SÍ Cuando reciba este tratamiento, tendrá que tomar medicamentos (como aglutinantes de fosfato).	SÍ Sin embargo, en comparación con la diálisis en el centro, es posible que tenga que tomar menos medicamentos (como los aglutinantes de fosfato).
¿Tendré síntomas como resultado de este tratamiento?	SÍ Puede presentar los siguientes síntomas: calambres musculares;	SÍ Sin embargo, en comparación con la diálisis en el centro, puede presentar

Características de la diálisis	Hemodiálisis en el centro	Máquina portátil de diálisis
	falta de aire; desmayos o mareos.	menos síntomas porque la sangre se limpia casi de forma continua.  Puede presentar: menos calambres musculares; menos falta de aire; menos desmayos o mareos; menos cansancio o agotamiento.

Antes de continuar, queremos hacerle algunas preguntas para asegurarnos de que entiende las diferencias entre estos tratamientos.

Which type of dialysis treatment requires you to visit a dialysis center 3 times per week?

In-center hemodialysis

Wearable dialysis device

None of the above

¿Qué tipo de tratamiento de diálisis exige que visite un centro de diálisis 3 veces por semana?

Hemodiálisis en el centro

Máquina portátil de diálisis

Ninguno de los anteriores

**[If Q9 != In-center hemodialysis]** Remember, In-center hemodialysis requires you to visit a dialysis center 3 times per week to get dialysis treatment. Wearable dialysis devices require you to visit a dialysis center only 1 time per month for a device and medical checkup.

**[If Q9 = In-center hemodialysis]** You are correct. In-center hemodialysis requires you to visit a dialysis center 3 times per week. Wearable dialysis devices require you to visit a dialysis center only 1 time per month for a device and medical checkup.

Which type of dialysis treatment requires you to take care of the device at home?

In-center hemodialysis

Wearable dialysis device

None of the above

¿Qué tipo de tratamiento de diálisis exige que cuide de la máquina en el hogar?

Hemodiálisis en el centro

Máquina portátil de diálisis

Ninguno de los anteriores

**If Q10 != Wearable dialysis device]** Remember, you would **not** need to take care of the dialysis machines used for In-center hemodialysis at home. You **would** be responsible for taking care of the wearable dialysis device at home. For example, you would need to clean the device regularly and be careful not to damage it.

**[If Q10 = Wearable dialysis device]** You are correct. You would be responsible for taking care of the wearable dialysis device at home. For example, you would need to clean the device regularly and be careful not to damage it.

You just learned about some of the differences between in-center hemodialysis and using a wearable dialysis device. Please rate how satisfied you would be with each type of dialysis on a scale of 0 to 10 (where 0 means “I would be very dissatisfied with this type of dialysis treatment” and 10 is “I would be very satisfied with this type of dialysis treatment”).

Acaba de conocer algunas de las diferencias entre la hemodiálisis en el centro y el uso de una máquina portátil de diálisis. Califique su grado de satisfacción con cada tipo de diálisis en la escala de 0 a 10 (tenga en cuenta que 0 indica que “estaría muy insatisfecho(a) con este tipo de tratamiento de diálisis” y 10 que “estaría muy satisfecho(a) con este tipo de tratamiento de diálisis”).

### For in-center hemodialysis

Very  
dissatisfied

Very  
satisfied

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Para hemodiálisis en el centro

Muy  
insatisfecho(a)

Muy  
satisfecho(a)

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### For the wearable dialysis device

Very  
dissatisfied

Very  
satisfied

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Para la máquina portátil de diálisis

Muy  
insatisfecho(a)

Muy  
satisfecho(a)

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## 2.3 Risk of Serious Bleeding

With any type of dialysis, there is a risk of serious bleeding from your dialysis access. The bleeding can be severe enough that you need help to stop the bleeding or need to go to the hospital for treatment. In rare cases, the bleeding can be bad enough to cause death.

If you are getting **in-center hemodialysis**, serious bleeding can happen if the catheter is accidentally disconnected from the dialysis machine or pulled from the skin. When you get dialysis through a fistula or graft, serious bleeding can happen if a needle gets accidentally pulled out from the fistula or graft or if the fistula or graft gets accidentally damaged. If you are in a dialysis center, the medical professionals would provide urgent care to stop the bleeding. If you are at home, you would need to get urgent medical care to stop the bleeding. Dialysis centers take many steps to prevent serious bleeding. Even if the dialysis center is careful, there is still a risk of serious bleeding.

If you are using a **wearable dialysis device**, serious bleeding can happen if the catheter gets accidentally disconnected from the device or pulled from the skin. You would need to get urgent medical care to stop the bleeding. The wearable dialysis device will be designed to prevent problems that lead to serious bleeding. In addition, you will get instructions on how to reduce the risk of bleeding. Even if you are careful, there will still be a risk of serious bleeding.

## 2.3 Riesgos de hemorragias intensas

Con cualquier tipo de diálisis, existe el riesgo de que se produzca una hemorragia intensa en el acceso de diálisis. La hemorragia puede ser lo suficientemente intensa como para necesitar ayuda para detenerla o tener que ir al hospital para recibir tratamiento. En ocasiones poco comunes, la hemorragia puede ser lo suficientemente intensa como para causar la muerte.

Si recibe **hemodiálisis en el centro**, pueden producirse hemorragias intensas si el catéter se desconecta accidentalmente de la máquina de diálisis o se arranca de la piel. Cuando se realiza la diálisis a través de una fístula o un injerto, pueden producirse hemorragias intensas si se extrae accidentalmente una aguja de la fístula o el injerto, o si la fístula o el injerto se dañan por accidente. Si acude a un centro de diálisis, los profesionales médicos le proporcionarán atención urgente para detener la hemorragia. Si se encuentra en su casa, tendría que recibir atención médica urgente para detener la hemorragia. Los centros de diálisis



toman muchas medidas para prevenir las hemorragias intensas. Aunque el centro de diálisis sea cuidadoso, sigue existiendo el riesgo de una hemorragia intensa.

Si utiliza una máquina portátil **de diálisis**, pueden producirse hemorragias intensas si el catéter se desconecta accidentalmente de la máquina o se arranca de la piel. Tendría que recibir atención médica urgente para detener la hemorragia. La máquina portátil de diálisis se diseñará para evitar problemas que provoquen hemorragias intensas. Además, recibirá instrucciones sobre cómo reducir el riesgo de hemorragia. Aunque tenga cuidado, seguirá existiendo el riesgo de una hemorragia intensa.

Has the catheter, fistula, or graft used in your current dialysis treatment ever become accidentally disconnected?

Yes

No

¿El catéter, la fístula o el injerto que se utilizan en su tratamiento de diálisis actual se desconectaron accidentalmente alguna vez?

Sí

No

On a scale from 0 to 10, how concerned are you about the risk of serious bleeding if the catheter, fistula, or graft used in your current dialysis machine becomes disconnected (where 0 indicates not at all concerned and 10 indicates that you are very concerned).

Not at all Concerned											Very Concerned
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

En una escala de 0 al 10, ¿cuál es su grado de preocupación por el riesgo de hemorragia intensa si se desconecta el catéter, la fístula o el injerto que se utiliza en su actual máquina de diálisis (tenga en cuenta que 0 indica que no le preocupa en absoluto y 10 que le preocupa mucho)?

No me preocupa en lo absoluto											Me preocupa mucho
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Compared to other people who get dialysis, do you think your risk of serious bleeding is:

Higher than other people

About the same as other people

Lower than other people

Don't know or not sure

En comparación con otras personas **que reciben diálisis**, ¿cree que su riesgo de sufrir hemorragias intensas es...?

Mayor que el de otras personas

Casi el mismo que el de otras personas

Menor que el de otras personas

No sé o no estoy seguro(a)

## 2.4 Risk of Serious Infection

With any type of dialysis, there is a risk of developing a serious infection from your dialysis treatment. If you develop a serious infection, you would need to see your doctor and be treated with antibiotics. You may have to go to a hospital for infection treatment. In some cases, the infection can be bad enough to cause death.

If you are getting **in-center hemodialysis**, an infection could get into your body through your dialysis access. This can happen when inserting needles into your fistula or graft, or when connecting or disconnecting your catheter to the dialysis machine. Dialysis centers take many steps to prevent serious infection. Even if the dialysis center is careful, there is still a risk of serious infection.

If you are using a **wearable dialysis device**, an infection could get into your body through the catheter. This could happen when you connect or disconnect the device. The wearable dialysis devices will be designed to prevent problems that lead to serious infection. In addition, you will get instructions on how to reduce the risk of infection. Even if you are careful, there is still a risk of serious infection.

## 2.4 Riesgo de infección grave

Con cualquier tipo de diálisis, existe el riesgo de que se produzcan infecciones graves a causa del tratamiento de diálisis. Si se produce una infección grave, tendrá que acudir al médico y recibir tratamiento con antibióticos. Es posible que tenga que ir a un hospital para el tratamiento de la infección. En algunas ocasiones, la infección puede ser lo suficientemente grave como para causar la muerte.

Si recibe **hemodiálisis en el centro**, podría entrar en el cuerpo una infección a través del acceso de diálisis. Esto puede ocurrir al insertar las agujas en la fístula o el injerto, o al conectar o desconectar el catéter a la máquina de diálisis. Los centros de diálisis toman muchas medidas para prevenir las infecciones graves. Aunque el centro de diálisis sea cuidadoso, sigue existiendo el riesgo de infecciones graves.

Si utiliza una máquina portátil **de diálisis**, podría entrar en el cuerpo una infección a través del catéter. Esto puede ocurrir al conectar o desconectar la máquina. Las máquinas portátiles de diálisis se diseñarán para evitar problemas que provoquen infecciones graves. Además, recibirá instrucciones sobre cómo reducir el riesgo de infecciones. Aunque tenga cuidado, seguirá existiendo el riesgo de contraer una infección grave.

Have you ever been hospitalized for a serious infection related to your dialysis treatment?

Yes

No

¿Alguna vez ha estado hospitalizado(a) a causa de una infección grave relacionada con el tratamiento de diálisis?

Sí

No

On a scale from 0 to 10, how concerned are you about the risk of a serious infection related to your dialysis treatment (where 0 indicates not at all concerned and 10 indicates that you are very concerned).

Not at all  
Concerned

Very  
Concerned

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

En una escala de 0 al 10, ¿cuál es su grado de preocupación por el riesgo de una infección grave relacionada con el tratamiento de diálisis (tenga en cuenta que 0 indica que no le preocupa en absoluto y 10 que le preocupa mucho)?

No me  
preocupa  
en lo  
absoluto

Me  
preocupa  
mucho

0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Compared to other people who get dialysis, do you think your risk of serious infection is:

Higher than other people

About the same as other people

Lower than other people

Don't know or not sure

En comparación con otras personas que reciben diálisis, ¿cree que su riesgo de sufrir infecciones graves es...?

Mayor que el de otras personas

Casi el mismo que el de otras personas

Menor que el de otras personas

No sé o no estoy seguro(a)

## 2.5 Thinking About the Risk from Dialysis

The survey will use pictures to help you think about the two risks from dialysis that we just described, the risk of serious bleeding and the risk of a serious infection.

Please look at the example picture below and think about the risk of serious infection.

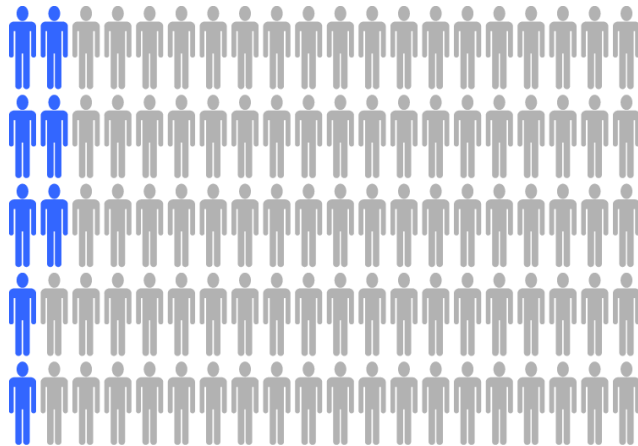
Each figure in the picture below represents 1 person who gets dialysis each year.

There are 100 figures in the picture.

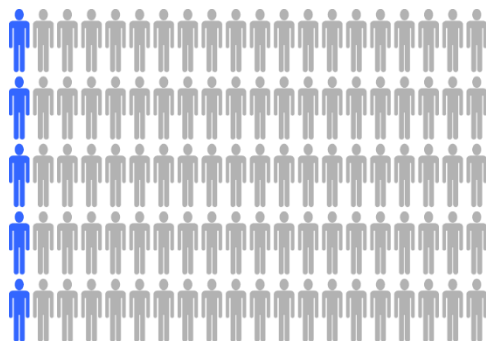
The figures shown in color show the number of people who have a serious infection from the dialysis device each year.

The figures in gray show the number of people who will not get a serious infection from the dialysis device each year.

### Example:



Please look at the picture below.



In this example, there are 8 figures in color. That means that 8 out of 100 people (8%) who use a dialysis device will develop a serious infection each year from the dialysis device.

There are 92 figures in gray. That means 92 out of 100 people (92%) who use a

## 2.5 Consideración del riesgo de la diálisis

En la encuesta se utilizarán imágenes para que pueda pensar en los dos riesgos de la diálisis que acabamos de describir, el riesgo de una hemorragia intensa y el riesgo de una infección grave.

Observe la imagen de ejemplo que aparece a continuación y piense en el riesgo de infección grave.

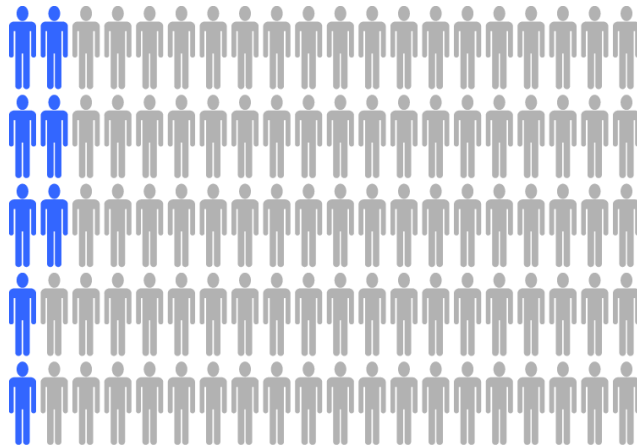
Cada figura de la siguiente imagen representa a 1 persona que recibe diálisis cada año.

Hay 100 figuras en la imagen.

Las figuras de color muestran la cantidad de personas que presentan infecciones graves a causa de la máquina de diálisis cada año.

Las figuras en gris muestran la cantidad de personas que no presentan ninguna infección grave a causa de la máquina de diálisis cada año.

Ejemplo:



En este ejemplo, hay 8 figuras de color.

Esto significa que 8 de cada 100 personas (8 %) que utilizan una máquina de diálisis tendrán una infección grave cada año a causa de la máquina de diálisis.

Hay 92 figuras en gris. Esto significa que 92 de cada 100 personas (92%) que utilizan una máquina de diálisis no desarrollarán una infección

If each figure is 1 person who gets dialysis each year and there are 100 figures in the picture, how many people who get dialysis in this example will get a serious infection? *(Please check only one answer).*

- 5 out of 100 people each year (5%)
- 40 out of 100 people each year (40%)
- 80 out of 100 people each year (80%)
- 95 out of 100 people each year (95%)
- Don't know or not sure

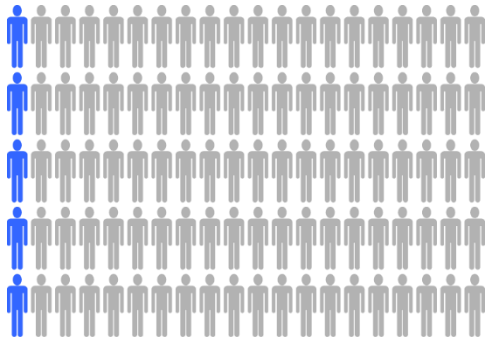
Si cada figura es 1 persona que recibe diálisis cada año y hay 100 figuras en la imagen, ¿cuántas personas que se someten a diálisis en este ejemplo contraerán una infección grave? *(Marque solo una respuesta).*

- 5 de cada 100 personas cada año (5 %)
- 40 de cada 100 personas cada año (40 %)
- 80 de cada 100 personas cada año (80 %)



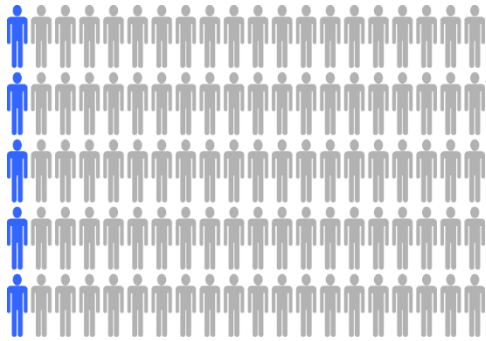
95 de cada 100 personas cada año (95 %)

No sé o no estoy seguro(a)



Remember, each figure represents 1 person who gets dialysis each year. In the picture above there are 100 figures and 5 of them are in color, while the rest are gray. This means that 5 out of 100 people (or 5%) who get dialysis each year will develop a serious infection. The correct answer is 5 out of 100 (5%).

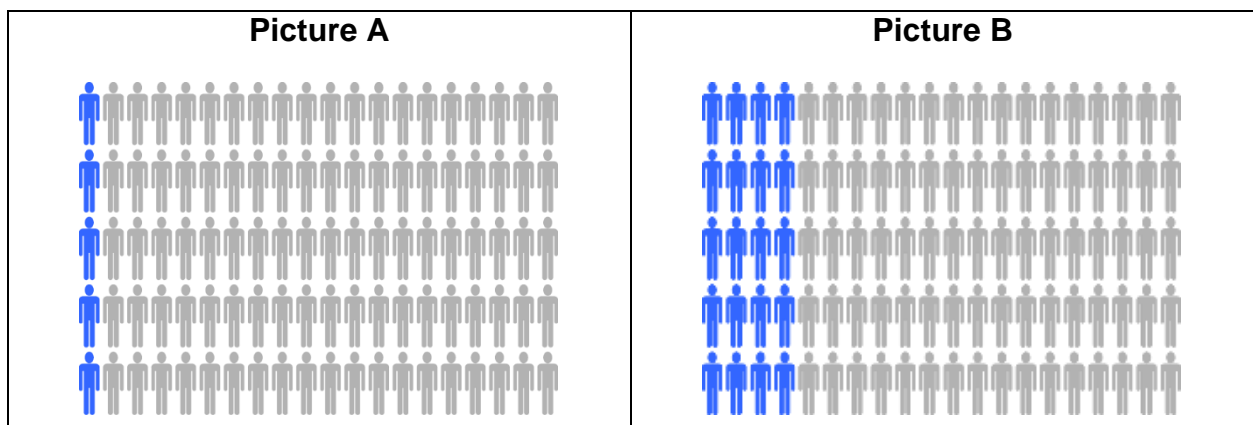
Recuerde que cada figura representa a 1 persona que recibe diálisis cada año. En la imagen de arriba hay 100 figuras y 5 de ellas son de color, mientras que el resto son grises. Esto significa que 5 de cada 100 personas (o el 5%) que reciben diálisis cada año tendrán una infección grave. La respuesta correcta es 5 de 100 (5 %).



You are correct. In the picture above there are 100 figures and 5 of them are in color, while the rest are gray. This means that 5 out of 100 people (or 5%) who get dialysis each year will develop a serious infection. The correct answer is 5 out of 100 (5%).

Correcto. En la imagen de arriba hay 100 figuras y 5 de ellas son de color, mientras que el resto son grises. Esto significa que 5 de cada 100 personas (o el 5 %) que reciben diálisis cada año tendrán una infección grave. La respuesta correcta es 5 de 100 (5 %).

Please look at the pictures below.



Which picture shows a greater risk of getting a serious infection?

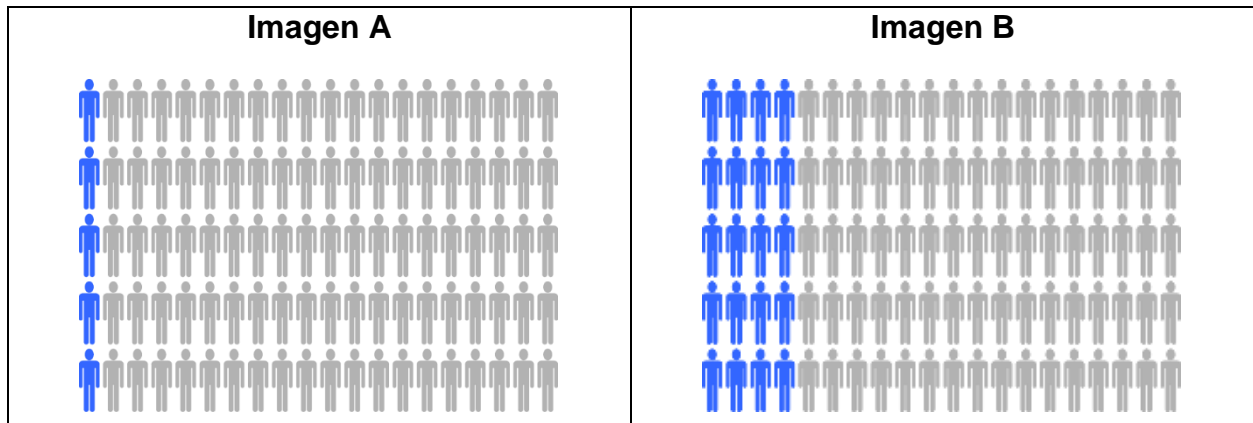
*(Please check only one answer).*

Picture A

Picture B

Don't know or not sure

Mire las imágenes de abajo.

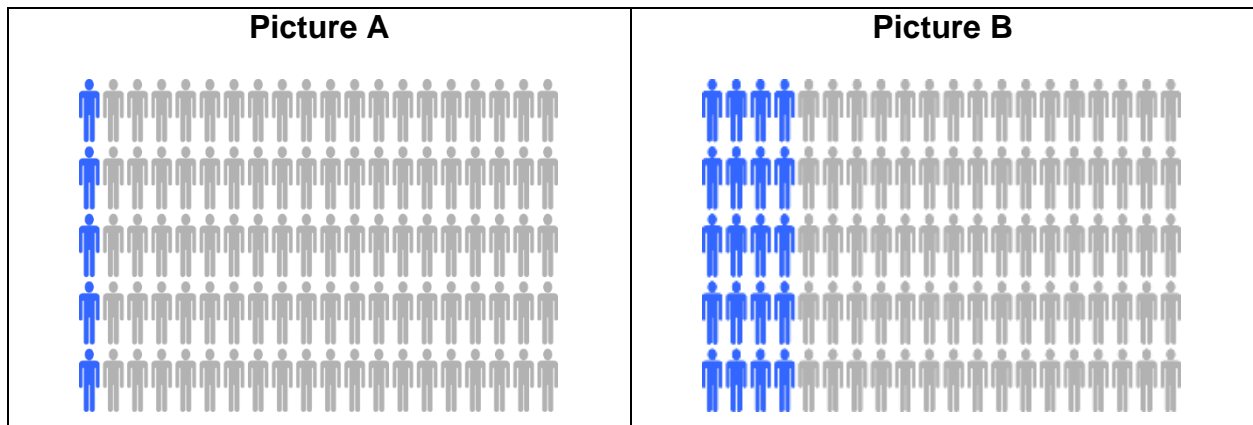


¿En qué imagen se ve un mayor riesgo de contraer una infección grave?  
(Marque solo una respuesta).

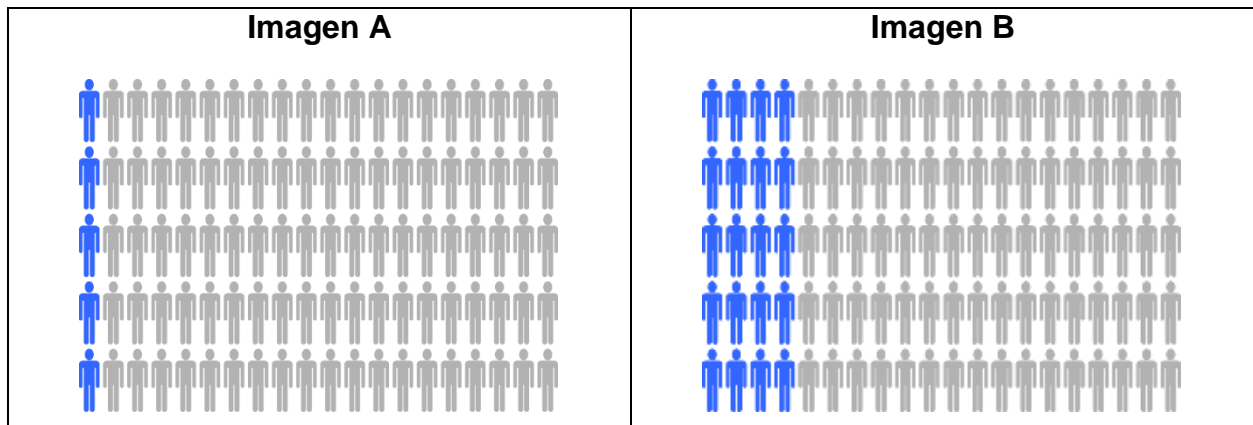
Imagen A

Imagen B

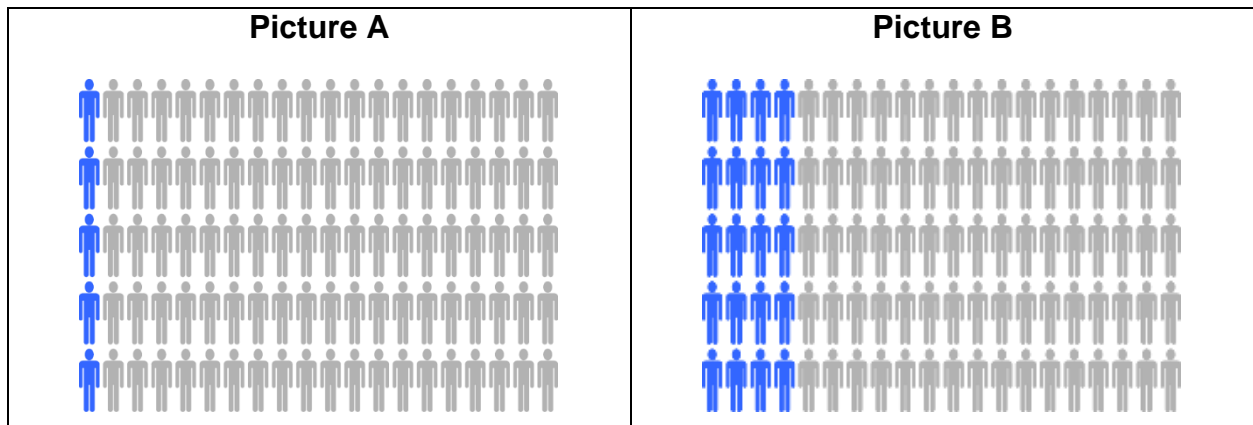
No sé o no estoy seguro(a)



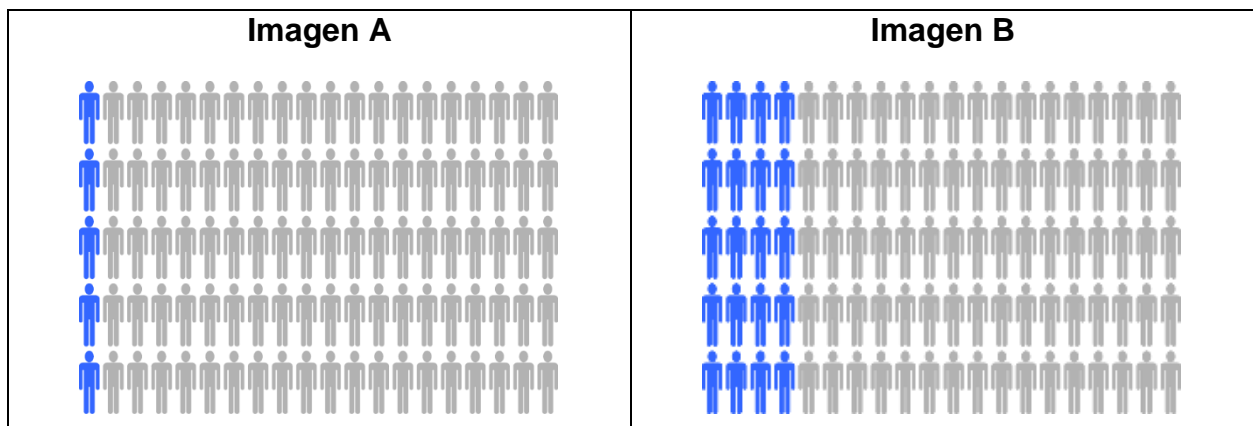
Remember, each figure represents 1 person who gets dialysis each year. There are 100 figures in each picture above. In Picture A, 5 of them are in color, while the rest are gray. This means that 5 out of 100 people (or 5%) who get dialysis each year will develop a serious infection. In Picture B, 20 figures are in color, while the rest are gray. This means that 20 out of 100 people (or 20%) who get dialysis each year will develop a serious infection. Because 20% is greater than 5%, the correct answer is Picture B.



Recuerde que cada figura representa a 1 persona que recibe diálisis cada año. Hay 100 figuras en cada una de las imágenes de arriba. En la imagen A, 5 de ellas son de color, mientras que el resto son grises. Esto significa que 5 de cada 100 personas (o el 5 %) que reciben diálisis cada año tendrán una infección grave. En la imagen B, 20 figuras son de color, mientras que el resto son grises. Esto significa que 20 de cada 100 personas (o el 20 %) que reciben diálisis cada año tendrán una infección grave. Como el 20 % es mayor que el 5 %, la respuesta correcta es la imagen B.



You are correct. There are 100 figures in each picture above. In Picture A, 5 of them are in color, while the rest are gray. This means that 5 out of 100 people (or 5%) who getting dialysis will develop a serious infection. In Picture B, 20 figures are in color, while the rest are gray. This means that 20 out of 100 people (or 20%) who are getting dialysis will develop a serious infection. Because 20% is greater than 5%, the correct answer is Picture B.



Correcto. Hay 100 figuras en cada una de las imágenes de arriba. En la imagen A, 5 de ellas son de color, mientras que el resto son grises. Esto significa que 5 de cada 100 personas (o el 5 %) que reciben diálisis tendrán una infección grave. En la imagen B, 20 figuras son de color, mientras que el resto son grises. Esto significa que 20 de cada 100 personas (o el 20 %) que reciben diálisis tendrán una infección grave. Como el 20 % es mayor que el 5 %, la respuesta correcta es la imagen B.

In the next few questions, we will ask you to think about whether you would prefer in-center hemodialysis or the wearable dialysis device when each method of dialysis has different risks of serious bleeding and serious infection

**[NOTE: Randomize order Section 2.5.1 and 2.5.2 are shown to respondents]**

### 2.5.1 Thinking About Risk of Serious Bleeding

We will start with the **risk of serious bleeding**. Look at the table below. The risk of serious bleeding differs for each type of treatment.

**For in-center hemodialysis:** Less than 1 out of 100 people (less than 1%) will have serious bleeding each year. Serious bleeding can occur if the catheter becomes disconnected or a needle becomes dislodged from a fistula or graft.

**For wearable dialysis device:** 8 out of 100 people (8%) will have serious bleeding each year. Serious bleeding can occur if the catheter becomes disconnected.

En las siguientes preguntas, le pediremos que piense si prefiere la hemodiálisis en el centro o la máquina portátil de diálisis cuando cada método de diálisis tiene diferentes riesgos de hemorragias intensas o infecciones graves.

**[NOTE: Randomize order Section 2.5.1 and 2.5.2 are shown to respondents]**

### 2.5.1 Consideración del riesgo de hemorragias intensas


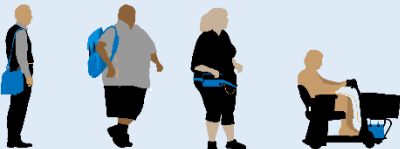
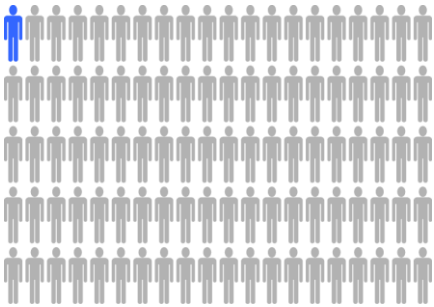
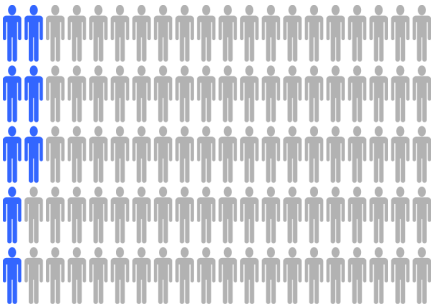
Empezaremos por el **riesgo de hemorragias intensas**. Mire la tabla de abajo. El riesgo de hemorragia intensa es diferente para cada tipo de tratamiento.

**En el caso de hemodiálisis en el centro:** menos de 1 de cada 100 personas (menos del 1 %) tendrá una hemorragia intensa cada año. Pueden producirse hemorragias intensas si el catéter se desconecta o una aguja se desprende de una fístula o un injerto.

**En el caso de la máquina portátil de diálisis:** 8 de cada 100 personas (8 %) tendrá una hemorragia intensa cada año. Pueden producirse hemorragias intensas si el catéter se desconecta.



For these questions, please focus on the risk of serious bleeding. Considering the benefits of in-center dialysis and a wearable dialysis device and the risk of serious bleeding, which would you choose? Please mark the box below your choice.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious bleeding each year	 <p>&lt;1 out of 100 people (&lt;1%)</p>	 <p>8 out of 100 people (8%)</p>
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

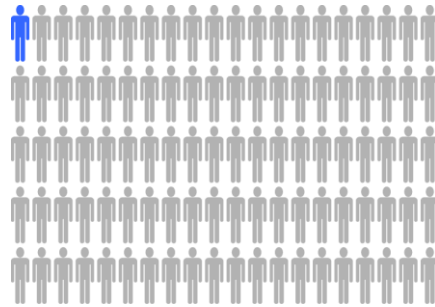
[If answer = 1 (In-center Hemodialysis) then go to 1a]

[If answer = 2 (Wearable device) then go to 1b]

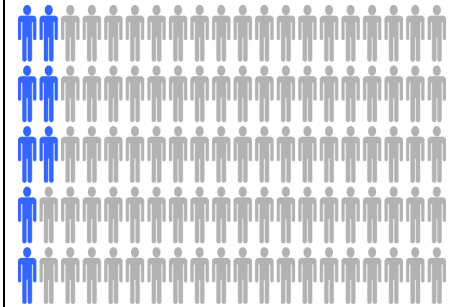
Para estas preguntas, concéntrese en el riesgo de hemorragias intensas. Si tiene en cuenta las ventajas de la diálisis en el centro y de una máquina portátil de diálisis y el riesgo de hemorragias intensas, ¿qué elegiría? Marque la casilla debajo de su elección.

	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		

**Riesgo de  
hemorragias  
intensas cada  
año**



<1 de cada 100 personas  
(<1 %)



8 de cada 100 personas  
(8 %)

**¿Qué opción  
elegiría?**


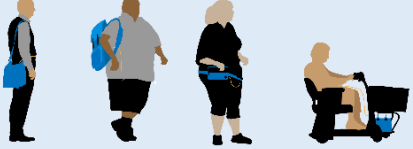
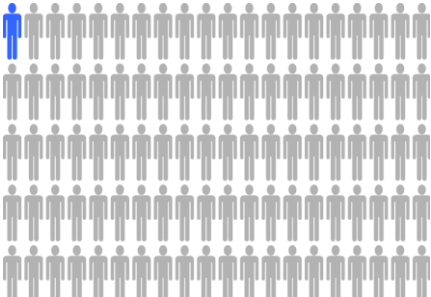
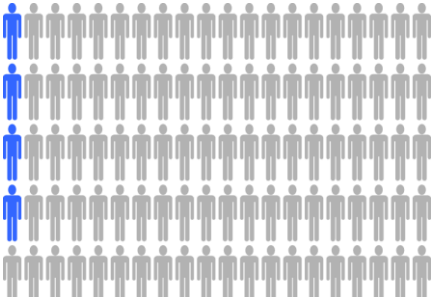




[If answer = 1 (In-center Hemodialysis) then go to 1a]

[If answer = 2 (Wearable device) then go to 1b]

[1a]

In the last question, you said that you preferred **in-center hemodialysis**. What if the risk of serious bleeding for the wearable dialysis device was 4%? Please look at the table below and select the option you would prefer.


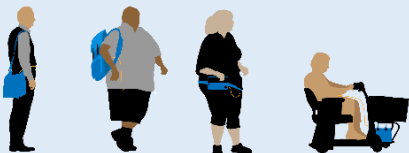
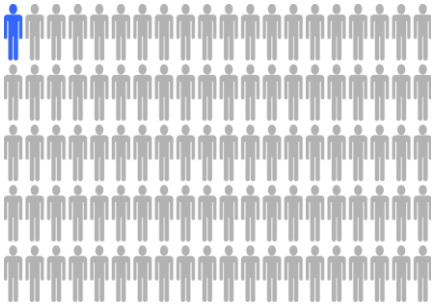
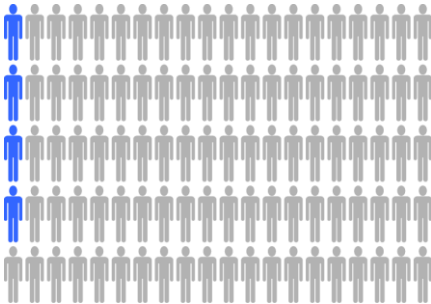
	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious bleeding each year	 <1 out of 100 people (<1%)	 4 out of 100 people (4%)
Which option would you choose?		

[If answer = 1 (Incenter Hemodialysis) then go to 1a.1]

[If answer = 2 (Wearable Dialysis Device) then go to 1a.2]

En la última pregunta, dijo que prefería la **hemodiálisis en el centro**. ¿Qué sucede si el riesgo de hemorragias intensas de la máquina portátil de diálisis fuera del 4 %?

Consulte la tabla de abajo y seleccione la opción que prefiera.



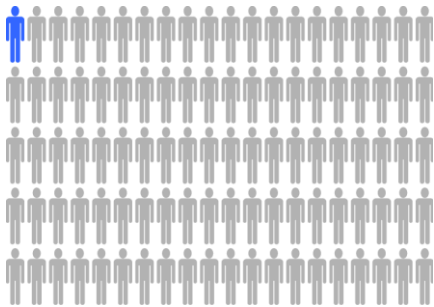
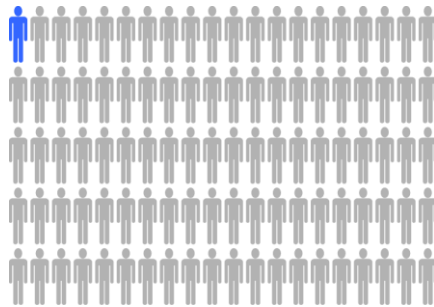
	Hemodiálisis en el centro	Máquina portátil de diálisis
<b>Cómo es la diálisis</b>		
<b>Riesgo de hemorragias intensas cada año</b>	 <p>&lt;1 de cada 100 personas (&lt;1 %)</p>	 <p>4 de cada 100 personas (4 %)</p>
<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (Incenter Hemodialysis) then go to 1a.1]

[If answer = 2 (Wearable Dialysis Device) then go to 1a.2]

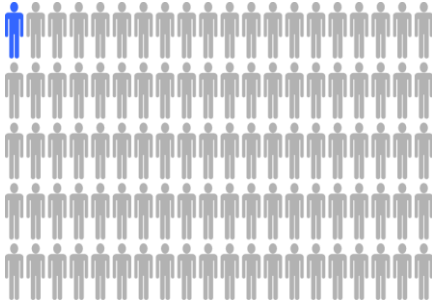
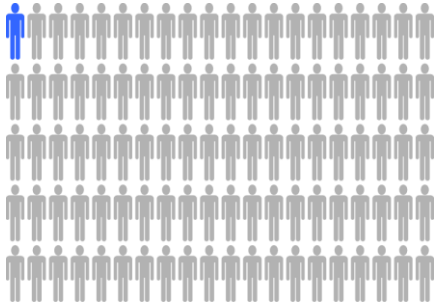
[1a.1]

In the last question, you said that you preferred **in-center hemodialysis**. What if the risk of serious bleeding for the wearable dialysis device was 1%? Please look at the table below and select the option you would prefer.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious bleeding each year	 <1 out of 100 people (<1%)	 1 out of 100 people (1%)
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

En la última pregunta, dijo que prefería la **hemodiálisis en el centro**. ¿Qué sucede si el riesgo de hemorragias intensas de la máquina portátil de diálisis fuera del 1 %? Consulte la tabla de abajo y seleccione la opción que prefiera.

	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		

<p><b>Riesgo de hemorragias intensas cada año</b></p>	 <p>&lt;1 de cada 100 personas (&lt;1 %)</p>	 <p>1 de cada 100 personas (1 %)</p>
<p><b>¿Qué opción elegiría?</b></p>	<div style="border: 2px solid black; width: 50px; height: 30px; margin: 0 auto;"></div>	<div style="border: 2px solid black; width: 50px; height: 30px; margin: 0 auto;"></div>

**[If select in-center]** In the last question, you said that you preferred in-center hemodialysis. Would you accept any risk of serious bleeding to use the wearable dialysis device?

Yes

No

Do not know or not sure

**[If select in-center]** En la última pregunta, dijo que prefería la hemodiálisis en el centro. ¿Aceptaría el riesgo de sufrir una hemorragia intensa para utilizar la máquina portátil de diálisis?



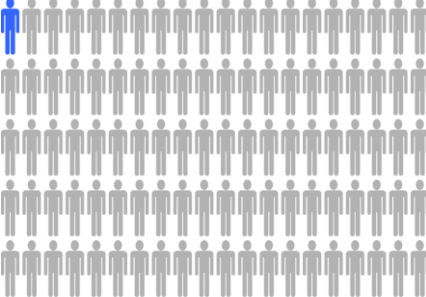
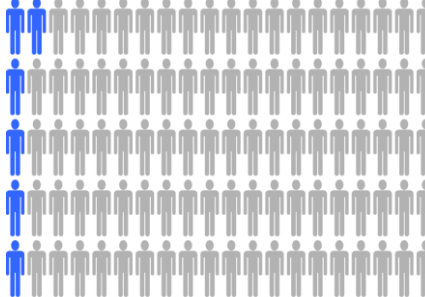
Sí

No

No sé o no estoy seguro(a)



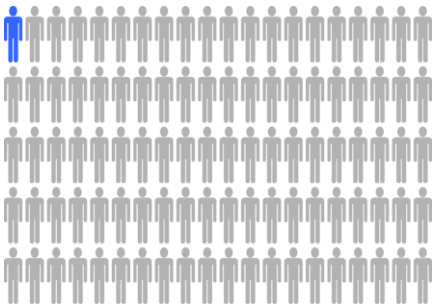
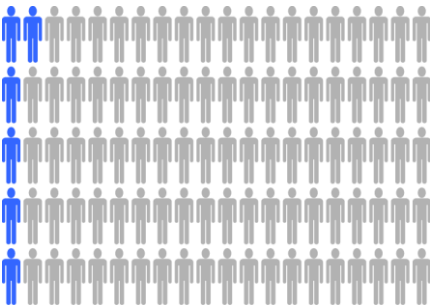
[1a.2]

In the last question, you said that you preferred **a wearable dialysis device**. What if the risk of serious bleeding for the wearable dialysis device was 6%? Please look at the table below and select the option you would prefer.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious bleeding each year	 <1 out of 100 people (<1%)	 6 out of 100 people (6%)
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>


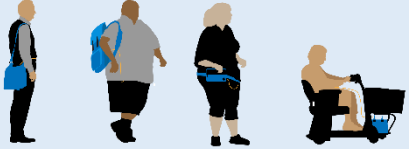
En la última pregunta, dijo que prefería la máquina portátil **de diálisis**. ¿Qué sucede si el riesgo de hemorragias intensas de la máquina portátil de diálisis fuera del 6 %?

Consulte la tabla de abajo y seleccione la opción que prefiera.

	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		
Riesgo de hemorragias intensas cada año	 <p>&lt;1 de cada 100 personas (&lt;1 %)</p>	 <p>6 de cada 100 personas (6 %)</p>
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

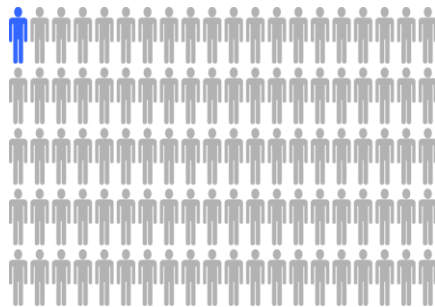
[1b]

In the last question, you said that you preferred **wearable dialysis device**. What if the risk of serious bleeding for the wearable dialysis device was 16%? Please look at the table below and select the option you would prefer.

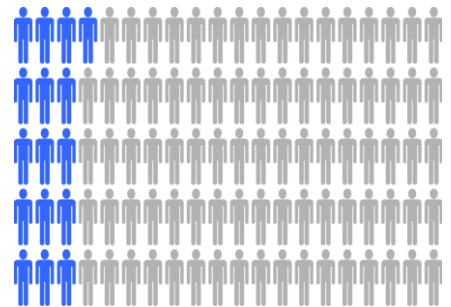
	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		



**Risk of serious bleeding each year**



<1 out of 100 people (<1%)



16 out of 100 people (16%)


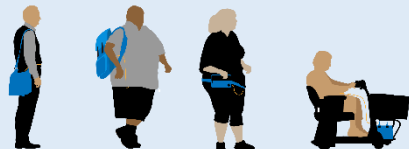
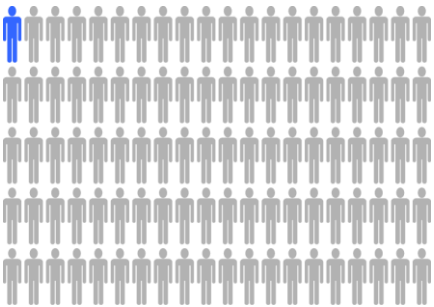
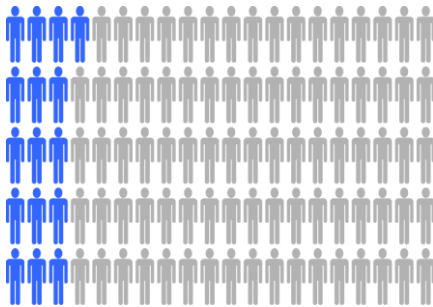
**Which option would you choose?**



[If answer = 1 (In-center Hemodialysis) then go to 1b.1]

[If answer = 2 (Wearable Dialysis Device) then go to 1b.2]

En la última pregunta, dijo que prefería la máquina portátil **de diálisis**. ¿Qué sucede si el riesgo de hemorragias intensas de la máquina portátil de diálisis fuera del 16 %? Consulte la tabla de abajo y seleccione la opción que prefiera.


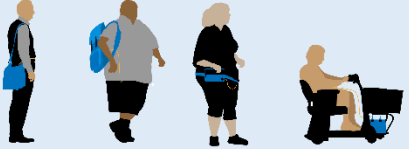
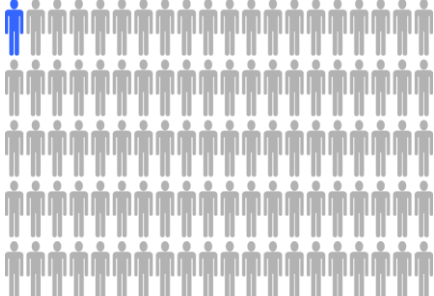
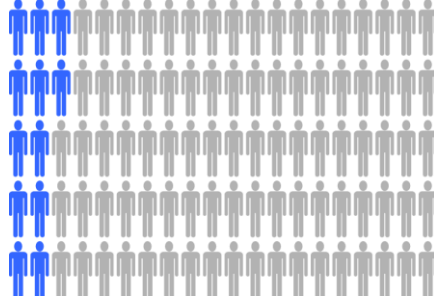


	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		
Riesgo de hemorragias intensas cada año	 <p>&lt;1 de cada 100 personas (&lt;1 %)</p>	 <p>16 de cada 100 personas (16 %)</p>
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (In-center Hemodialysis) then go to 1b.1]



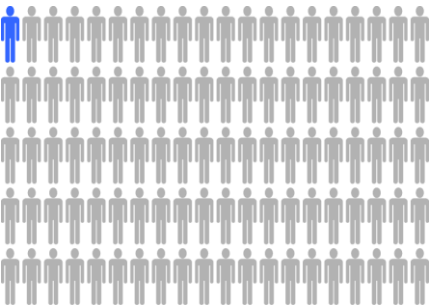
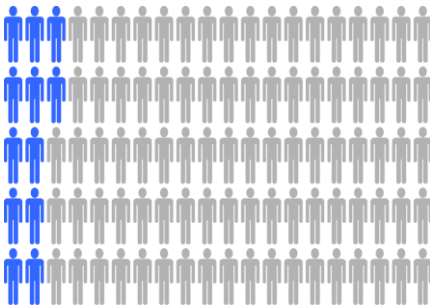
[If answer = 2 (Wearable Dialysis Device) then go to 1b.2]

[1b.1]

In the last question, you said that you preferred **in-center hemodialysis**. What if the risk of serious bleeding was for the wearable dialysis device 12%? Please look at the table below and select the option you would prefer.


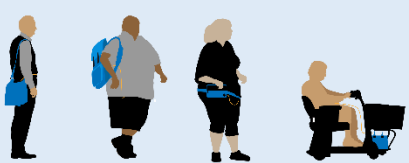
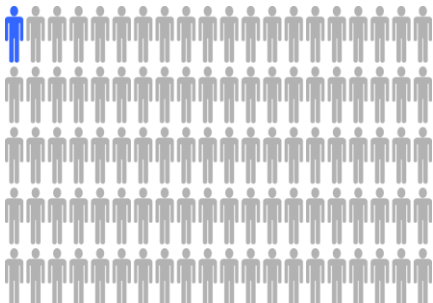
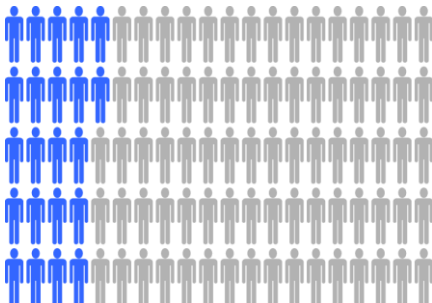


	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious bleeding each year	 <1 out of 100 people (<1%)	 12 out of 100 people (12%)
Which option would you choose?		

En la última pregunta, dijo que prefería la **hemodiálisis en el centro**. ¿Qué sucede si el riesgo de hemorragias intensas de la máquina portátil de diálisis fuera del 12 %? Consulte la tabla de abajo y seleccione la opción que prefiera.

	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		
Riesgo de hemorragias intensas cada año	 <p>&lt;1 de cada 100 personas (&lt;1 %)</p>	 <p>12 de cada 100 personas (12 %)</p>
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

[1b.2]


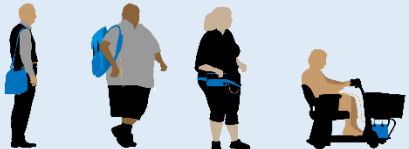
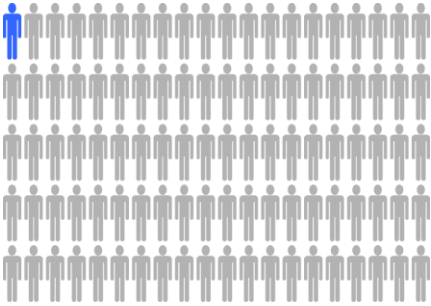
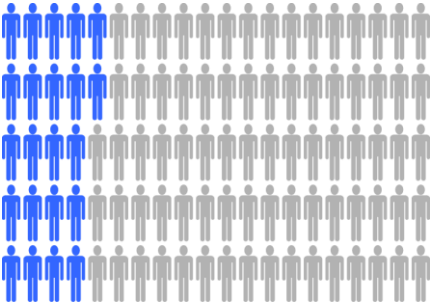
In the last question, you said that you preferred **a wearable dialysis device**. What if the risk of serious bleeding for the wearable dialysis device was 22%? Please look at the table below and select the option you would prefer.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious bleeding each year	 <1 out of 100 people (<1%)	 22 out of 100 people (22%)
Which option would you choose?		

**[If selected wearable]** In the last question, you said that you would choose to get the wearable dialysis device that had a 22% risk of serious bleeding. What is the highest risk of serious bleeding that you would be willing to accept to get the wearable dialysis device?

\_\_\_\_\_ %

En la última pregunta, dijo que prefería la máquina portátil **de diálisis**. ¿Qué sucede si el riesgo de hemorragias intensas de la máquina portátil de diálisis fuera del 22 %? Consulte la tabla de abajo y seleccione la opción que prefiera.

	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		
Riesgo de hemorragias intensas cada año	 <p>&lt;1 de cada 100 personas (&lt;1 %)</p>	 <p>22 de cada 100 personas (22 %)</p>
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

**[If selected wearable]** En la última pregunta, dijo que elegiría la máquina portátil de diálisis que tenía un 22 % de riesgo de hemorragias intensas. ¿Cuál es el mayor riesgo de hemorragias intensas que estaría dispuesto(a) a aceptar para conseguir la máquina portátil de diálisis?

\_\_\_\_\_ %

## 2.5.2 Thinking About Risk of Serious Infection

Next, we will ask you to think about the **risk of serious infection**. Look at the table below. The risk of serious infection differs for each type of treatment.

**For in-center hemodialysis:** 6 out of 100 people (6%) will get a serious infection each year.

**For wearable dialysis device:** 31 out of 100 people (31%) will get a serious infection each year.


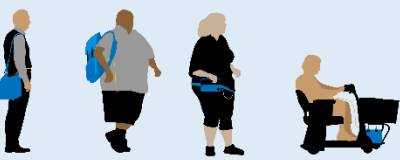
## 2.5.2 Consideración del riesgo de infecciones graves

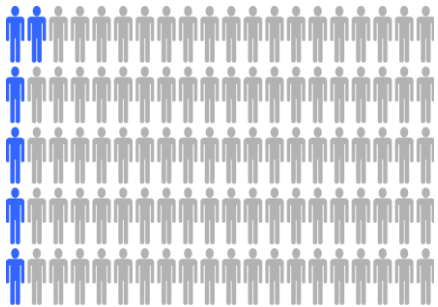
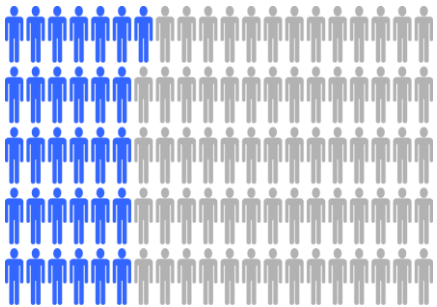
A continuación, le pediremos que piense en el **riesgo de infecciones graves**. Mire la tabla de abajo. El riesgo de infecciones graves difiere para cada tipo de tratamiento.

**En el caso de hemodiálisis en el centro:** 6 de cada 100 personas (6 %) tendrá una infección grave cada año.

**En el caso de la máquina portátil de diálisis:** 31 de cada 100 personas (31 %) tendrá una infección grave cada año.

For these questions, please focus on the risk of serious infection. Considering the benefits of in-center dialysis and a wearable dialysis device and the risk of serious infection, which would you choose? Please mark the box below your choice.


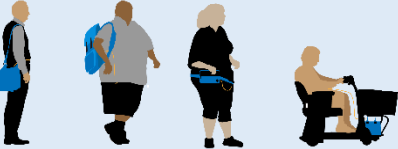
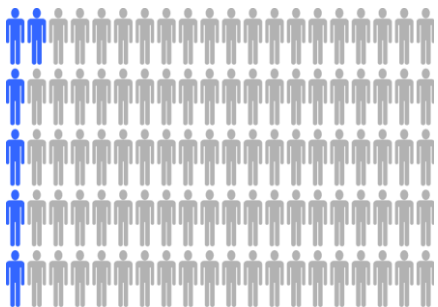
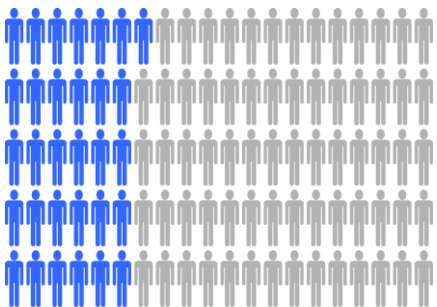
	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		

<p><b>Risk of serious infection each year</b></p>	 <p>6 out of 100 people (6%)</p>	 <p>31 out of 100 people (31%)</p>
<p><b>Which option would you choose?</b></p>	<div data-bbox="659 653 750 718" style="border: 2px solid black; width: 56px; height: 31px; margin: 0 auto;"></div>	<div data-bbox="1157 653 1248 718" style="border: 2px solid black; width: 56px; height: 31px; margin: 0 auto;"></div>

[If answer = 1 (In-center Hemodialysis) then go to 2a]

[If answer = 2 (Wearable device) then go to 2b]

Para estas preguntas, concéntrese en el riesgo de infecciones graves. Si tiene en cuenta las ventajas de la diálisis en el centro y de una máquina portátil de diálisis y el riesgo de infecciones graves, ¿qué elegiría? Marque la casilla debajo de su elección.

	<p><b>Hemodiálisis en el centro</b></p>	<p><b>Máquina portátil de diálisis</b></p>
<p><b>Cómo es la diálisis</b></p>		
<p><b>Riesgo de infecciones importantes cada año</b></p>	 <p>6 de cada 100 personas (6 %)</p>	 <p>31 de cada 100 personas (31 %)</p>



¿Qué opción  
elegiría?


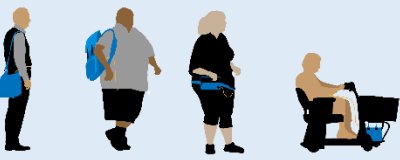
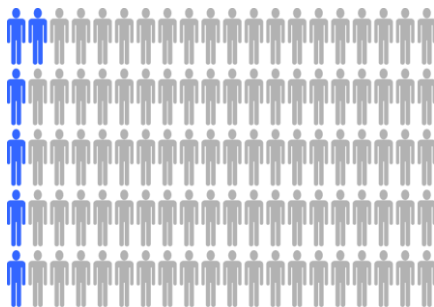
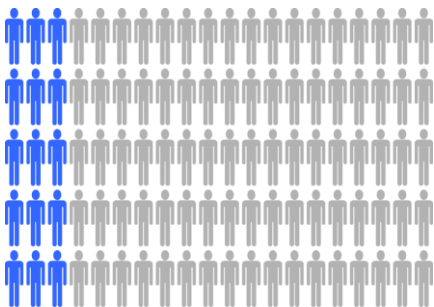




[If answer = 1 (In-center Hemodialysis) then go to 2a]

[If answer = 2 (Wearable device) then go to 2b]

[2a]

In the last question, you said that you preferred **in-center hemodialysis**. What if the risk of serious infection for the wearable dialysis device was 15%? Please look at the table below and select the option you would prefer.

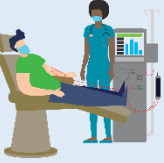
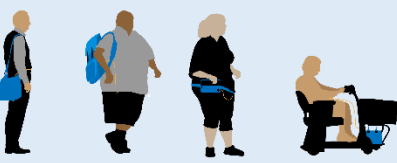
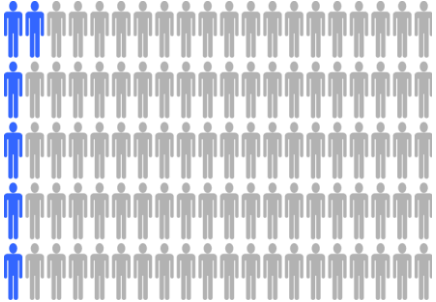
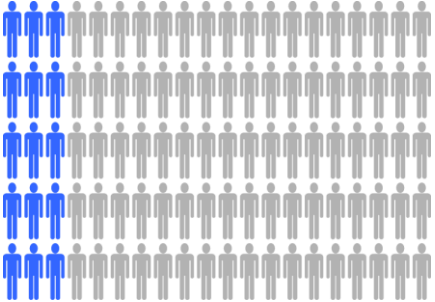
	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious infection each year	 6 out of 100 people (6%)	 15 out of 100 people (15%)
Which option would you choose?		

[If answer = 1 (Incenter Hemodialysis) then go to 2a.1]

[If answer = 2 (Wearable Dialysis Device) then go to 2a.2]

En la última pregunta, dijo que prefería la **hemodiálisis en el centro**. ¿Qué sucede si el riesgo de infecciones graves concerniente la máquina portátil de diálisis fuera del 15 %? Consulte la tabla de abajo y seleccione la opción que prefiera.

Hemodiálisis en el centro	Máquina portátil de diálisis
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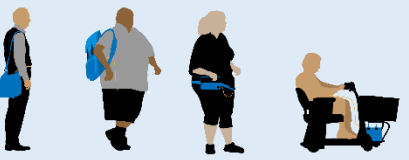
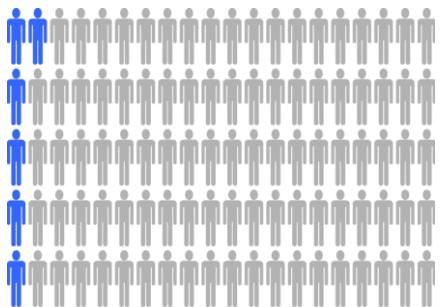
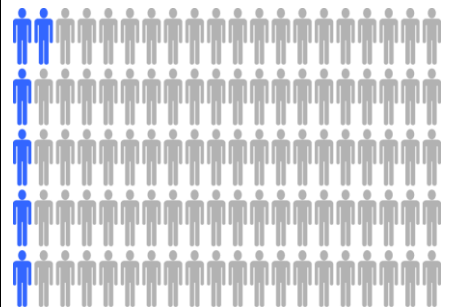
<p><b>Cómo es la diálisis</b></p>		
<p><b>Riesgo de infecciones graves cada año</b></p>	 <p>6 de cada 100 personas (6 %)</p>	 <p>15 de cada 100 personas (15 %)</p>
<p><b>¿Qué opción elegiría?</b></p>	<div data-bbox="659 905 750 968" style="border: 2px solid black; width: 56px; height: 30px; margin: 0 auto;"></div>	<div data-bbox="1159 905 1250 968" style="border: 2px solid black; width: 56px; height: 30px; margin: 0 auto;"></div>

[If answer = 1 (Incenter Hemodialysis) then go to 2a.1]

[If answer = 2 (Wearable Dialysis Device) then go to 2a.2]


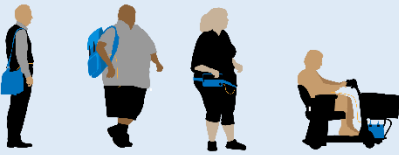
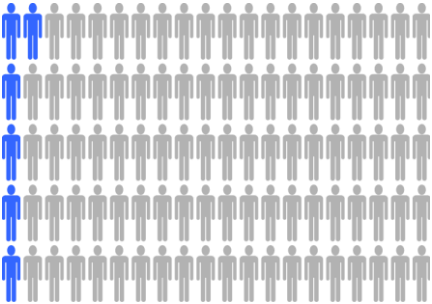
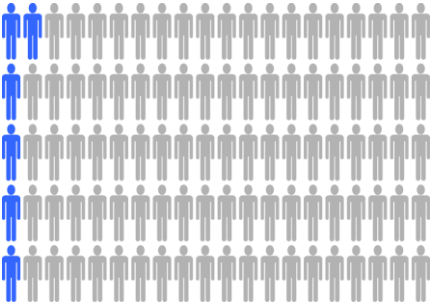


[2a.1]

In the last question, you said that you preferred **in-center hemodialysis**. What if the risk of serious infection for the wearable dialysis device was 6%? Please look at the table below and select the option you would prefer.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious infection each year	 6 out of 100 people (6%)	 6 out of 100 people (6%)
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

En la última pregunta, dijo que prefería la **hemodiálisis en el centro**. ¿Qué sucede si el riesgo de infecciones graves de la máquina portátil de diálisis fuera del 6 %? Consulte la tabla de abajo y seleccione la opción que prefiera.

Hemodiálisis en el centro	Máquina portátil de diálisis
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<p><b>Cómo es la diálisis</b></p>		
<p><b>Riesgo de infecciones graves cada año</b></p>	 <p>6 de cada 100 personas (6 %)</p>	 <p>6 de cada 100 personas (6 %)</p>
<p><b>¿Qué opción elegiría?</b></p>		

**[If answer in-center]** In the last question, you said that you preferred in-center hemodialysis. Would you accept any risk of serious infection to use the wearable dialysis device?

Yes

No

Do not know or not sure

**[If answer in-center]** En la última pregunta, dijo que prefería la hemodiálisis en el centro. ¿Aceptaría cualquier riesgo de padecer una infección grave para utilizar la máquina portátil de diálisis?


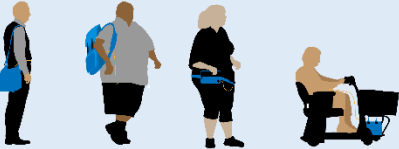
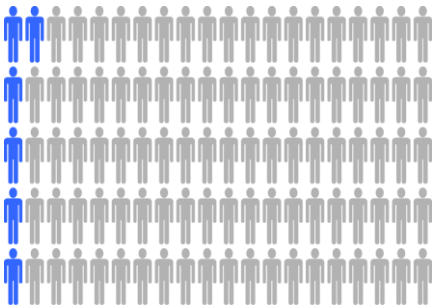
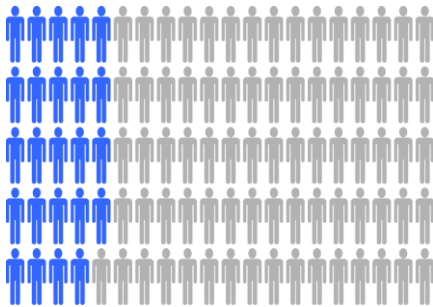
Sí

No

No sé o no estoy seguro(a)


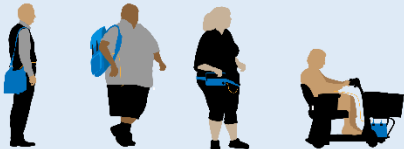
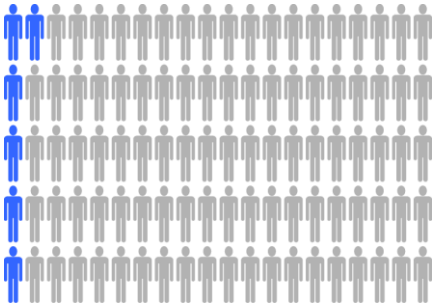
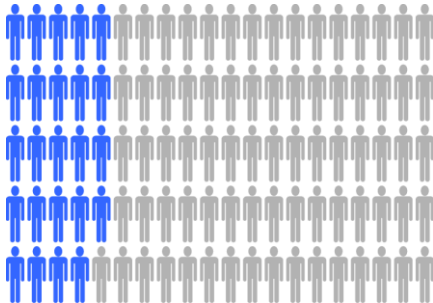
[2a.2]

In the last question, you said that you preferred **a wearable dialysis device**. What if the risk of serious infection for the wearable dialysis device was 24%? Please look at the table below and select the option you would prefer.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious infection each year	 6 out of 100 people (6%)	 24 out of 100 people (24%)
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>


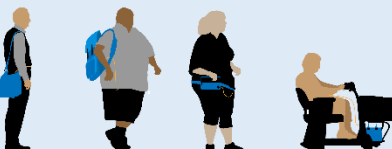
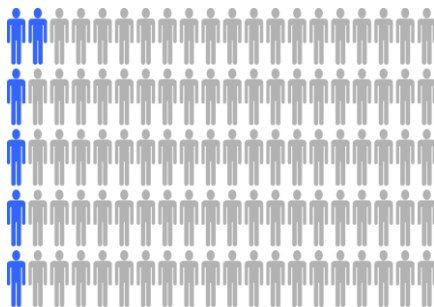
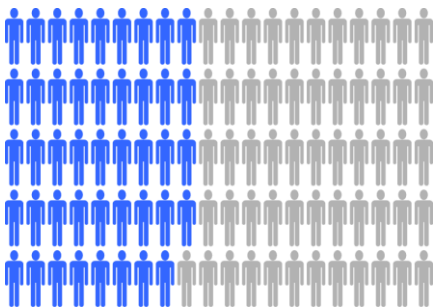
En la última pregunta, dijo que prefería la **máquina portátil de diálisis**. ¿Qué sucede si el riesgo de infecciones graves de la máquina portátil de diálisis fuera del 24 %?

Consulte la tabla de abajo y seleccione la opción que prefiera.

	Hemodiálisis en el centro	Máquina portátil de diálisis
<b>Cómo es la diálisis</b>		
<b>Riesgo de infecciones graves cada año</b>	 <p>6 de cada 100 personas (6 %)</p>	 <p>24 de cada 100 personas (24 %)</p>
<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[2b]

In the last question, you said that you preferred **wearable dialysis device**. What if the risk of serious infection for the wearable dialysis device was 44%? Please look at the table below and select the option you would prefer.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious infection each year	 6 out of 100 people (6%)	 44 out of 100 people (44%)
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (In-center Hemodialysis) then go to 2b.1] on page 38 of respondent version


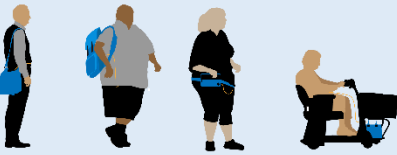
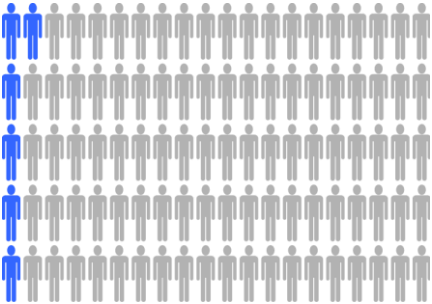
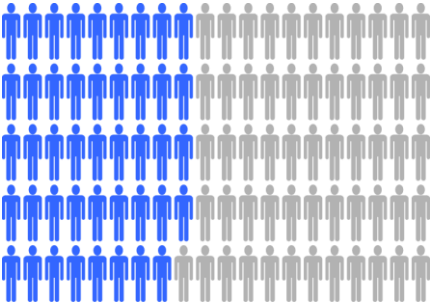


[If answer = 2 (Wearable Dialysis Device) then go to 2b.2] on page 39 of respondent version

En la última pregunta, dijo que prefería **la máquina portátil de diálisis**. ¿Qué sucede si el riesgo de infecciones graves de la máquina portátil de diálisis fuera del 44 %?

Consulte la tabla de abajo y seleccione la opción que prefiera.


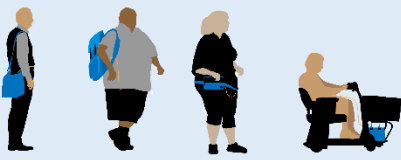
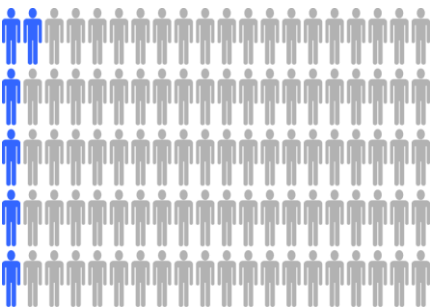
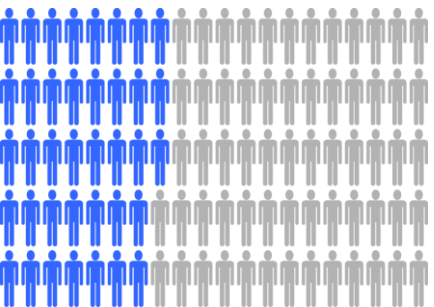
Hemodiálisis en el centro	Máquina portátil de diálisis
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<p><b>Cómo es la diálisis</b></p>		
<p><b>Riesgo de infecciones graves cada año</b></p>	 <p>6 de cada 100 personas (6 %)</p>	 <p>44 de cada 100 personas (44 %)</p>
<p><b>¿Qué opción elegiría?</b></p>		

[2b.1]

In the last question, you said that you preferred **in-center hemodialysis**. What if the risk of serious infection for the wearable dialysis device was 38%? Please look at the table below and select the option you would prefer.

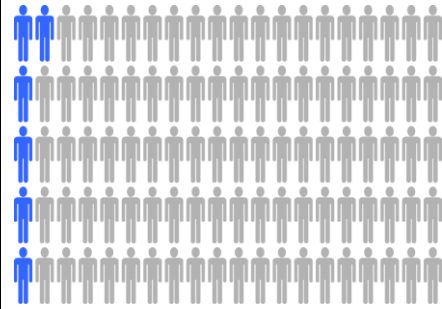
	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious infection each year	 6 out of 100 people (6%)	 38 out of 100 people (38%)
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

En la última pregunta, dijo que prefería la **hemodiálisis en el centro**. ¿Qué sucede si el riesgo de infecciones graves de la máquina portátil de diálisis fuera del 38 %?

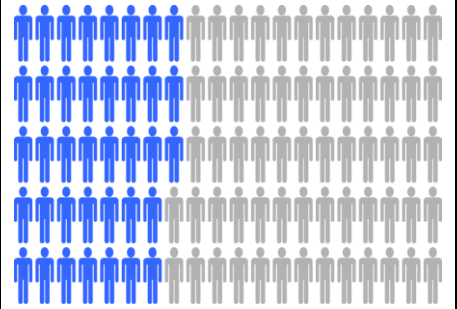
Consulte la tabla de abajo y seleccione la opción que prefiera.

	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		

**Riesgo de  
infecciones graves  
cada año**



6 de cada 100 personas  
(6 %)




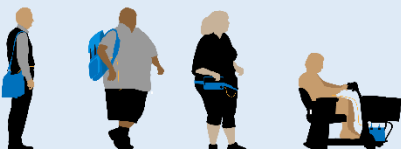
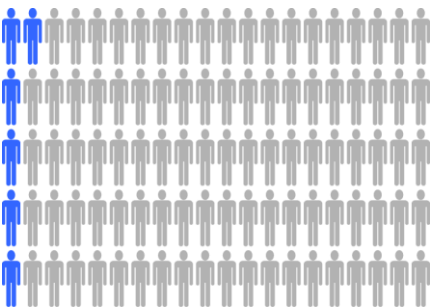
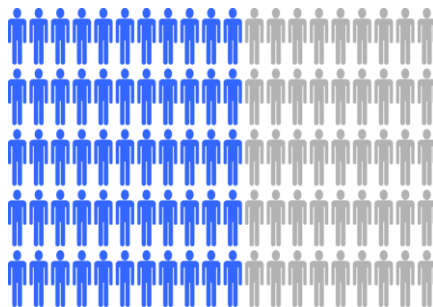
38 de cada 100 personas  
(38 %)

**¿Qué opción  
elegiría?**



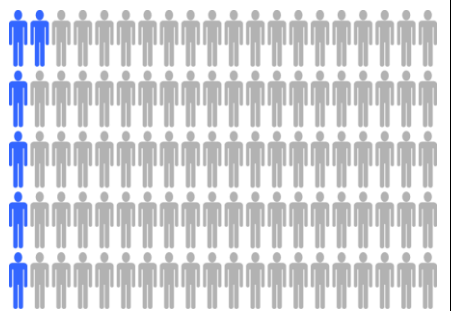
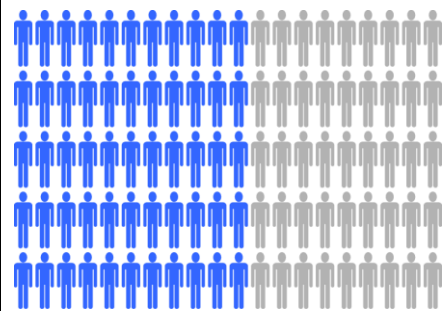
[2b.2]

In the last question, you said that you preferred **a wearable dialysis device**. What if the risk of serious infection for the wearable dialysis device was 55%? Please look at the table below and select the option you would prefer.

	In-center hemodialysis	Wearable dialysis device
What the dialysis is like		
Risk of serious infection each year	 6 out of 100 people (6%)	 55 out of 100 people (55%)
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

En la última pregunta, dijo que prefería la máquina portátil **de diálisis**. ¿Qué sucede si el riesgo de infecciones graves concerniente la máquina portátil de diálisis fuera del 55 %? Consulte la tabla de abajo y seleccione la opción que prefiera.

	Hemodiálisis en el centro	Máquina portátil de diálisis
Cómo es la diálisis		

<b>Riesgo de infecciones graves cada año</b>	 <p>6 de cada 100 personas (6 %)</p>	 <p>55 de cada 100 personas (55 %)</p>
	<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>

In the last question, you said that you would choose to get the wearable dialysis device that had a 55% risk of serious infection. What is the highest risk of serious infection that you would be willing to accept to get the wearable dialysis device?

\_\_\_\_\_ %

En la última pregunta, dijo que elegiría la máquina portátil de diálisis que tenía un 55 % de riesgo de padecer una infección grave. ¿Cuál es el mayor riesgo de infecciones graves que estaría dispuesto(a) a aceptar para conseguir la máquina portátil de diálisis?

\_\_\_\_\_ %

### 3. How Long You Would Wait for New Wearable Dialysis Devices

[Randomly assign each respondent to either the serious bleeding or the serious infection series. Ideally, we would like this to be truly randomized so as to avoid concerns with ordering effects.]

[Serious bleeding series, Show this section if respondent was willing to accept risk of serious bleeding >0 for device in previous questions]

Over time, we expect wearable dialysis devices will get better as technology improves. In the future, wearable dialysis devices may have a lower risk of serious bleeding.

Some people might be willing to accept a higher risk of bleeding to get a wearable dialysis device now. However, other people might choose to wait for technology to improve to get a wearable dialysis device that has a lower risk of bleeding in the future.

Now we are going to ask you to think about how long you would be willing to wait to get a wearable dialysis device that has a lower risk of serious bleeding.

Earlier you told us that you would be interested in a wearable dialysis device if the risk of serious bleeding was **[X% = highest risk at which respondent selected wearable device, if respondent never selected a wearable device in the previous questions then they should not see these questions]**.

Imagine that the Food and Drug Administration (FDA) is trying to decide whether to approve a wearable device like the devices described in this survey.

The FDA could approve Wearable Dialysis Device A **now**. The device currently has a [X%] risk of serious bleeding.

OR the FDA could let the company that makes the device continue working on the device to reduce the risk of serious bleeding. If the FDA waits **3 years** to approve Wearable Dialysis Device A, the risk of serious bleeding will be [X% – (0.5\*X%)]%. During the 3 years you wait for FDA to approve the device, you will get in-center dialysis.

Aside from the difference in the risk of serious bleeding, the device would be exactly the same in 3 years as it is now.

### 3. Cuánto tiempo estaría dispuesto(a) a esperar por las nuevas máquinas portátiles de diálisis

[Randomly assign each respondent to either the serious bleeding or the serious infection series. Ideally, we would like this to be truly randomized so as to avoid concerns with ordering effects.]

[Serious bleeding series, Show this section if respondent was willing to accept risk of serious bleeding >0 for device in previous questions]

Con el tiempo, esperamos que las máquinas portátiles de diálisis mejoren a medida que lo haga la tecnología. En el futuro, las máquinas portátiles de diálisis podrían tener un menor riesgo de hemorragias intensas.

Algunas personas podrían estar dispuestas a aceptar un mayor riesgo de hemorragia para obtener una máquina portátil de diálisis ahora. Sin embargo, otras personas pueden optar por esperar a que la tecnología mejore para conseguir una máquina portátil de diálisis que tenga un menor riesgo de hemorragia en el futuro.

Ahora vamos a pedirle que piense cuánto tiempo estaría dispuesto(a) a esperar para conseguir una máquina portátil de diálisis que tenga un menor riesgo de hemorragia intensa.

Anteriormente, nos dijo que estaría interesado(a) en una máquina portátil de diálisis si el riesgo de hemorragia intensa fuera del [X% = highest risk at which respondent selected wearable device, if respondent never selected a wearable device in the previous questions then they should not see these questions]..

Imagínese que la Administración de Alimentos y Medicamentos intenta decidir si aprueba una máquina portátil como los descritos en esta encuesta.

La FDA podría aprobar ya la máquina portátil de diálisis A. En este momento, la máquina tiene un [X %] de riesgo de hemorragia intensa.

O la FDA podría dejar que la empresa que fabrica la máquina siga trabajando en él para reducir el riesgo de hemorragias intensas. Si la FDA espera **3 años** para aprobar la máquina portátil de diálisis A, el riesgo de hemorragias intensas será del [X % a (0.5\*X %)]%. Durante los 3 años que espera a que la FDA apruebe la máquina, recibirá diálisis en el centro.

Aparte de la diferencia en el riesgo de hemorragias intensas, la máquina será exactamente el mismo dentro de 3 años que ahora.

Looking at the information below, please tell us whether you would want a wearable dialysis device now or in 3 years. Please check the box below to mark your choice.

	Approve Wearable Dialysis A Device Now	Approve Wearable Dialysis Device A in 3 Years
<b>Risk of serious bleeding</b>	Insert risk graphic and words [X%] risk	Insert risk graphic and words [X% – (0.5*X%)] risk
<b>Time until you get the device</b>	Now	3 years
<b>Which option would you choose?</b>	<input type="checkbox"/>	<input type="checkbox"/>



[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T1a]

[If answer = 2 (Approve Wearable Dialysis Device A in 3 Years) then go to T1b]

Si tiene en cuenta la siguiente información, díganos si querrá una máquina portátil de diálisis ahora o dentro de 3 años. Marque la casilla debajo de su elección.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 3 años
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<b>Riesgos de hemorragias intensas</b>	Insert risk graphic and words [X%] risk	Insert risk graphic and words [X% – (0.5*X%)] risk
<b>Tiempo hasta la obtención de la máquina</b>	Ahora	En 3 años
<b>¿Qué opción elegiría?</b>		

[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T1a]

[If answer = 2 (Approve Wearable Dialysis Device A in 3 Years) then go to T1b]

[T1a]

[If T1 = 1 (NOW)]

In the last question, you said that you wanted to get Wearable Dialysis Device A now. What if you only had to wait 1 year to reduce the risk of serious bleeding? Please look at the information below and select the option you would prefer.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 1 Year
Risk of serious bleeding	[insert risk gride and words for X%]	[insert risk gride and words for $X\% - (0.5 \cdot X\%)$ ]
Time until you get the device	Now	1 year
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T1a.1]

[If answer = 2 (Approve Wearable Dialysis Device A in 1 Year) then go to T1a.2]

En la última pregunta, dijo que quería obtener la máquina portátil de diálisis A ahora.

¿Qué sucede si solo tuviera que esperar 1 año para reducir el riesgo de hemorragias intensas? Consulte la información de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 1 año
	<input type="checkbox"/>	<input type="checkbox"/>

<b>Riesgos de hemorragias intensas</b>	[insert risk gride and words for X%]	[insert risk gride and words for $X\% - (0.5 \cdot X\%)$ ]
<b>Tiempo hasta la obtención de la máquina</b>	Ahora	En 1 año
<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T1a.1]

[If answer = 2 (Approve Wearable Dialysis Device A in 1 Year) then go to T1a.2]

**[T1a.1]**

**[If T1a = 1 (NOW)]**

In the last question, you said that you wanted to get Wearable Dialysis Device A now.

Would you wait any amount of time to reduce the risk of serious bleeding?

Yes

No

Do not know or not sure

**[if Yes] 1 \_\_\_\_\_ months**

**[End—Go to next series or next section]**

En la última pregunta, dijo que quería obtener la máquina portátil de diálisis A ahora.

¿Esperaría cualquier cantidad de tiempo para reducir el riesgo de una hemorragia intensa?

Sí

No

No sé o no estoy seguro(a)

**[if Yes] 1 \_\_\_\_\_ meses**

**[End—Go to next series or next section]**

[T1a.2]

[If T1a = 2 (WAIT)]

In the last question, you said that you would wait 1 year to get Wearable Dialysis Device A. Would you wait 2 years? Please look at the information below and select the option you would prefer.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 2 Year
Risk of serious bleeding	[insert risk gride and words for X%]	[insert risk gride and words for $X\% - (0.5 \cdot X\%)$ ]
Time until you get the device	Now	2 years
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]

En la última pregunta, dijo que esperaría 1 año para obtener la máquina portátil de diálisis A. ¿Esperaría 2 años? Consulte la información de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 2 años

<b>Riesgos de hemorragias intensas</b>	[insert risk gride and words for X%]	[insert risk gride and words for X% – (0.5*X%)]
<b>Tiempo hasta la obtención de la máquina</b>	Ahora	En 2 años
<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]

[T1b]

[If T1 = 2 (WAIT)]

In the last question, you said that you would wait 3 years to get Wearable Dialysis Device A. What if you had to wait 6 years to reduce the risk of serious bleeding? Please look at the information below and select the option you would prefer.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 6 Year
Risk of serious bleeding	[insert risk gride and words for X%]	[insert risk gride and words for $X\% - (0.5 \cdot X\%)$ ]
Time until you get the device	Now	6 years
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 Approve Wearable Dialysis Device A Now then go to T1b.1]

[If answer = 2 Approve Wearable Dialysis Device A in 6 Year then go to T1b.2]

En la última pregunta, dijo que esperaría 3 años para conseguir la máquina portátil de diálisis A. ¿Qué pasaría si tuviera que esperar 6 años para reducir el riesgo de hemorragias intensas? Consulte la información de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 6 años

<b>Riesgos de hemorragias intensas</b>	[insert risk gride and words for X%]	[insert risk gride and words for $X\% - (0.5 \cdot X\%)$ ]
<b>Tiempo hasta la obtención de la máquina</b>	Ahora	En 6 años
<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 Approve Wearable Dialysis Device A Now then go to T1b.1]

[If answer = 2 Approve Wearable Dialysis Device A in 6 Year then go to T1b.2]



[T1b.1]

[If T1b = 1 (NOW)]

In the last question, you said that you preferred to get Wearable Dialysis Device A now. Would you wait 5 years? Please look at the information below and select the option you would prefer.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 5 Year
Risk of serious bleeding	[insert risk gride and words for X%]	[insert risk gride and words for $X\% - (0.5 \cdot X\%)$ ]
Time until you get the device	Now	5 years
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]

En la última pregunta, dijo que prefería obtener la máquina portátil de diálisis A ahora. ¿Esperaría 5 años? Consulte la información de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 5 años

Riesgos de hemorragias intensas	[insert risk gride and words for X%]	[insert risk gride and words for $X\% - (0.5 \cdot X\%)$ ]
Tiempo hasta la obtención de la máquina	Ahora	En 5 años
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]

**[T1b.2]**

**[If Question T1b = 2 (WAIT)]**

In the last question, you said that you would wait 6 years to get Wearable Dialysis Device A. What is the highest number of years that you would be willing to wait to get Wearable Dialysis Device A?

\_\_\_\_\_ years

**[End—Go to next series or next section]**

En la última pregunta, dijo que esperaría 6 años para conseguir la máquina portátil de diálisis A. ¿Cuál es la mayor cantidad de años que estaría dispuesto(a) a esperar para obtener la máquina portátil de diálisis A?

\_\_\_\_\_ años

**[End—Go to next series or next section]**

**[Serious infection series, Show this section if respondent was willing to accept risk of serious infection >0 for device in previous questions]**

Over time, we expect wearable dialysis devices will get better as technology improves. In the future, wearable dialysis devices may have a lower risk of serious infection.

Some people might be willing to accept a higher risk of infection to get a wearable dialysis device now. However, other people might choose to wait for technology to improve to get a wearable dialysis device that has a lower risk of infection in the future.

Now we are going to ask you to think about how long you would be willing to wait to get a wearable dialysis device that has a lower risk of serious infection.

Earlier you told us that you would be interested in a wearable dialysis device if the risk of serious infection was **[Y% = highest risk at which respondent selected wearable device if respondent never selected a wearable device in the previous questions then they should not see these questions]**.

Imagine that the Food and Drug Administration (FDA) is trying to decide whether to approve a wearable device like the devices described in this survey.

The Wearable Dialysis Device A could be approved **now**. The device currently has a **[Y%]** risk of serious infection.

OR the company that makes the device could continue working on the device to reduce the risk of serious infection. If the company waits **3 years** for the Wearable Dialysis Device A to be approved, the risk of serious infection will be **[Y% - (0.5\*Y%)]%**. During the 3 years you wait for the device to be approved, you will get in-center dialysis.

Aside from the difference in the risk of serious infection, the device would be exactly the same in 3 years as it is now.

Con el tiempo, esperamos que las máquinas portátiles de diálisis mejoren a medida que lo haga la tecnología. En el futuro, las máquinas portátiles de diálisis podrían tener un menor riesgo de infecciones graves.

Algunas personas podrían estar dispuestas a aceptar un mayor riesgo de infección para obtener una máquina portátil de diálisis ahora. Sin embargo, otras personas pueden optar por esperar a que la tecnología mejore para conseguir una máquina portátil de diálisis que tenga un menor riesgo de infección en el futuro.

Ahora vamos a pedirle que piense cuánto tiempo estaría dispuesto(a) a esperar para conseguir una máquina portátil de diálisis que tenga un menor riesgo de infección grave.

Anteriormente, nos dijo que estaría interesado(a) en una máquina portátil de diálisis si el riesgo de infección grave fuera del **[Y% = highest risk at which respondent selected wearable device if respondent never selected a wearable device in the previous questions then they should not see these questions]**.

Imagínese que la Administración de Alimentos y Medicamentos (FDA) intenta decidir si aprueba una máquina portátil como los descritos en esta encuesta.

La máquina portátil de diálisis A puede aprobarse **ya**. En este momento, la máquina tiene un **[Y%]** riesgo de infección intensa.

O la empresa que fabrica la máquina puede seguir trabajando en él para reducir el riesgo de infecciones intensas. Si la empresa espera **3 años** para aprobar la máquina portátil de diálisis A, el riesgo de infecciones graves será del **[Y% - (0.5\*Y%)]%**. Durante los 3 años de espera hasta que se apruebe la máquina, recibirá diálisis en el centro.

Aparte de la diferencia en el riesgo de infecciones graves, la máquina será exactamente el mismo dentro de 3 años que ahora.

Looking at the information below, please tell us whether you would want a wearable dialysis device now or in 3 years. Please check the box below to mark your choice.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 3 Years
<b>Risk of serious infection</b>	Insert risk graphic and words [Y%] risk	Insert risk graphic and words [Y% – (0.5*Y%)] risk
<b>Time until you get the device</b>	Now	3 years
<b>Which option would you choose?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T2a in Appendix]

[If answer = 2 (Approve Wearable Dialysis Device A in 3 Years) then go to T2b in Appendix]

Si tiene en cuenta la siguiente información, díganos si querrá una máquina portátil de diálisis ahora o dentro de 3 años. Marque la casilla debajo de su elección.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 3 años
_____	_____	_____

<b>Riesgos de infecciones graves</b>	Insert risk graphic and words [Y%] risk	Insert risk graphic and words [Y% – (0.5*Y%)] risk
<b>Tiempo hasta la obtención de la máquina</b>	Ahora	En 3 años
<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T2a in Appendix]

[If answer = 2 (Approve Wearable Dialysis Device A in 3 Years) then go to T2b in Appendix]

## [RISK OF SERIOUS INFECTION]

### [T2a]

#### [If T2 = 1 (NOW)]

In the last question, you said that you preferred to get Wearable Dialysis Device A now. What if you only had to wait 1 year to reduce the risk of serious infection? Please look at the table below and select the option you would prefer.

	<b>Approve Wearable Dialysis Device A Now</b>	<b>Approve Wearable Dialysis Device A in 1 Years</b>
--	---	--

<b>Risk of serious infection</b>	[insert risk gride and words for Y%]	[insert risk gride and words for $Y\% - (0.5 \cdot Y\%)$ ]
<b>Time until you get the device</b>	Now	1 year
<b>Which option would you choose?</b>	<div style="border: 2px solid black; width: 50px; height: 30px; margin: 0 auto;"></div>	<div style="border: 2px solid black; width: 50px; height: 30px; margin: 0 auto;"></div>

[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T2a.1]

[If answer = 2 (Approve Wearable Dialysis Device A in 1 Years) then go to T2a.2]



En la última pregunta, dijo que prefería obtener la máquina portátil de diálisis A ahora.  
 ¿Qué sucede si solo hubiera que esperar 1 año para reducir el riesgo de infecciones graves? Consulte la tabla de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 1 año
Riesgos de infecciones graves	[insert risk gride and words for Y%]	[insert risk gride and words for $Y\% - (0.5*Y\%)$ ]
Tiempo hasta la obtención de la máquina	Ahora	En 1 año
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 (Approve Wearable Dialysis Device A Now) then go to T2a.1]

[If answer = 2 (Approve Wearable Dialysis Device A in 1 Years) then go to T2a.2]

[T2a.1]

[If T2a = 1 (NOW)]

In the last question, you said that you preferred to get Wearable Dialysis Device A now.  
Would you wait any amount of time to reduce the risk of serious infection?

Yes

No

Do not know or not sure

[if Yes] I would be willing to wait \_\_\_\_\_ months

[End—Go to next series or next section]

En la última pregunta, dijo que prefería obtener la máquina portátil de diálisis A ahora.  
¿Esperaría cualquier cantidad de tiempo para reducir el riesgo de una infección grave?

Sí

No

No sé o no estoy seguro(a)

[if Yes] Estaría dispuesto(a) a esperar \_\_\_\_\_ meses.

[T2a.2]

[If T2a = 2 (WAIT)]

In the last question, you said that you would wait 1 year get Wearable Dialysis Device A. Would you wait 2 years until Wearable Dialysis Device A was available? Please look at the information below and select the option you would prefer.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 2 Years
Risk of serious infection	[insert risk gride and words for Y%]	[insert risk gride and words for $Y\% - (0.5*Y\%)$ ]
Time until you get the device	Now	2 years
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]

En la última pregunta, dijo que esperaría 1 año para conseguir la máquina portátil de diálisis A. ¿Esperaría 2 años hasta que la máquina portátil de diálisis estuviera disponible? Consulte la información de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 2 años

<b>Riesgos de infecciones graves</b>	[insert risk grille and words for Y%]	[insert risk grille and words for $Y\% - (0.5 \cdot Y\%)$ ]
<b>Tiempo hasta la obtención de la máquina</b>	Ahora	En 2 años
<b>¿Qué opción elegiría?</b>	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]

[T2b]

[If T2 = 2 (WAIT)]

In the last question, you said that you would wait 3 year to get Wearable Dialysis Device A. What if you had to wait 6 years to reduce the risk of serious infection? Please look at the information below and select the option you would prefer.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 6 Years
Risk of serious infection	[insert risk gride and words for Y%]	[insert risk gride and words for $Y\% - (0.5*Y\%)$ ]
Time until you get the device	Now	6 years
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 Approve Wearable Dialysis Device A Now then go to T2b.1]

[If answer = 2 Approve Wearable Dialysis Device A in 2 Years then go to T2b.2]

En la última pregunta, dijo que esperaría 3 años para obtener la máquina portátil de diálisis A. ¿Qué pasaría si tuviera que esperar 6 años para reducir el riesgo de infecciones graves? Consulte la información de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 6 años
	<input type="checkbox"/>	<input type="checkbox"/>

Riesgos de infecciones graves	[insert risk gride and words for Y%]	[insert risk gride and words for $Y\% - (0.5*Y\%)$ ]
Tiempo hasta la obtención de la máquina	Ahora	En 6 años
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

[If answer = 1 Approve Wearable Dialysis Device A Now then go to T2b.1]

[If answer = 2 Approve Wearable Dialysis Device A in 2 Years then go to T2b.2]

[T2b.1]

[If T2b = 1 (NOW)]

In the last question, you said that you wanted to get Wearable Dialysis Device A now. Would you wait 5 years? Please look at the table below and select the option you would prefer.

	Approve Wearable Dialysis Device A Now	Approve Wearable Dialysis Device A in 5 Years
Risk of serious infection	[insert risk gride and words for Y%]	[insert risk gride and words for $Y\% - (0.5*Y\%)$ ]
Time until you get the device	Now	5 years
Which option would you choose?	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]

En la última pregunta, dijo que quería obtener la máquina portátil de diálisis A ahora. ¿Esperaría 5 años? Consulte la tabla de abajo y seleccione la opción que prefiera.

	Aprobar la máquina portátil de diálisis A ahora	Aprobar la máquina portátil de diálisis A en 5 años
	<input type="checkbox"/>	<input type="checkbox"/>

Riesgos de infecciones graves	[insert risk grille and words for Y%]	[insert risk grille and words for $Y\% - (0.5 \cdot Y\%)$ ]
Tiempo hasta la obtención de la máquina	Ahora	En 5 años
¿Qué opción elegiría?	<input type="checkbox"/>	<input type="checkbox"/>

[End—Go to next series or next section]



**[T2b.2]**

**[If Question T2b = 2 (WAIT)]**

In the last question, you said that you would wait 6 years to get Wearable Dialysis Device A. What is the highest number of years that you would be willing to wait to get Wearable Dialysis Device A?

\_\_\_\_\_ years

**[End—Go to next series or next section]**

En la última pregunta, dijo que esperaría 6 años para obtener la máquina portátil de diálisis A. ¿Cuál es la mayor cantidad de años que estaría dispuesto(a) a esperar para obtener la máquina portátil de diálisis A?

\_\_\_\_\_ años

## 4. Other Questions About You

### Otras preguntas sobre usted

Do you have a caregiver or partner who assists with your dialysis care? For example, goes to dialysis appointments with you or helps you with your dialysis treatments?

Yes

No

¿Tiene un cuidador o un(a) compañero(a) que lo(a) ayuda con el cuidado de la diálisis? Por ejemplo, ¿acude alguien a las citas de diálisis con usted o lo(a) ayuda con sus tratamientos de diálisis?

Sí

No

Which of the following best describes your employment status?

*(Check only one answer.)*

Employed full-time

Employed part-time

Self-employed

Homemaker

Student

Retired

Disabled/Unable to work

Unemployed but looking for work

Unemployed and not looking for work

Prefer not to answer

¿Cuál de las siguientes opciones describe mejor su situación laboral?  
(Marque solo una respuesta).

Trabajo de tiempo completo

Trabajo de tiempo parcial

Trabajo de forma independiente

Me encargo de los quehaceres domésticos

Estudio

Me jubilé

Tengo una discapacidad/incapacidad para trabajar

No tengo trabajo, pero estoy buscando

No tengo trabajo, pero no estoy buscando

Prefiero no decirlo

How much difficulty do you have doing your daily physical activities, because of your health?

No difficulty at all

A little bit of difficulty

Some difficulty

A lot of difficulty

Can't do because of my health

¿En qué medida tiene dificultades para realizar sus actividades físicas diarias debido a su salud?

Ninguna dificultad

Un poco de dificultad

Algo de dificultad

Mucha dificultad

No puedo hacer nada debido a mi salud

To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?

Completely

Mostly

Moderately

A little

Not at all

¿En qué medida puede realizar sus actividades físicas cotidianas, como caminar, subir escaleras, llevar la compra o mover una silla?

Completamente

Casi siempre

Moderadamente

Un poco

Nunca

Do you have any of the following challenges that might make it difficult to use a wearable dialysis device? (*Select all that apply*)

Vision problems

Hearing problems

Memory problems

Difficulty with your hands, such as picking up and using small objects

Any other challenges that might make it difficult to use a wearable dialysis device  
(please specify)

None

¿Tiene alguna de las siguientes dificultades que podrían perjudicar el uso de la máquina portátil de diálisis? *(Seleccione todas las opciones que correspondan)*

Problemas de visión

Problemas de audición

Problemas de memoria

Dificultad con las manos, como recoger y utilizar objetos pequeños

Cualquier otro problema que pueda perjudicar el uso de una máquina portátil de diálisis (especifique)

Ninguna

Please rate how much you agree or disagree with the following statements:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I can manage my kidney disease as well as most other people					
I can find solutions for problems that occur with managing my kidney disease					

Indique en qué medida está de acuerdo o en desacuerdo con las siguientes declaraciones:

	Muy en desacuerdo	En desacuerdo	Ni de acuerdo ni en desacuerdo	De acuerdo	Muy de acuerdo
Puedo controlar mi enfermedad renal tan bien como la mayoría de las personas.					
Puedo encontrar soluciones a los problemas que surgen en el manejo de mi enfermedad renal.					

How confident are you filling out medical forms by yourself?

Extremely

Quite a bit

Somewhat

A little bit

Not at all

¿Cuánta confianza tiene en llenar los formularios médicos por sí mismo(a)?

Extremadamente

Bastante

Algo

Un poco

Nada

How often do you have someone help you read hospital materials?

All the time

Most of the time

Some of the time

None of the time

¿Con qué frecuencia tiene a alguien que lo(a) ayude a leer el material del hospital?

Todo el tiempo

La mayor parte del tiempo

Algunas veces

Nunca

How often do you have problems learning about your medical condition because of difficulty understanding written information?

All of the time

Most of the time

Some of the time

A little bit of the time

None of the time

¿Con qué frecuencia tiene problemas para informarse sobre su condición médica debido a la dificultad para entender la información escrita?

Todo el tiempo

La mayor parte del tiempo

Algunas veces

Pocas veces

Nunca

## Thank You!

Thank you for completing this survey! The wearable dialysis devices described in this survey are currently being developed and are not yet available for patients. Your input on this survey will be very helpful to those developing these devices. Your participation and survey answers are confidential and cannot be linked to you.

We will send a \$35 electronic gift card to you by email. Please provide your email address below. We will send the card in 1-2 weeks after you complete the survey.

- Email address: \_\_\_\_\_

[For participants recruited through clinics only]

We will send a \$35 electronic gift card to you by email. Please provide your email address below. We will send the card in 1-2 weeks after you complete the survey.

- Email address: \_\_\_\_\_



If you prefer to receive a gift card by mail, please provide your name and mailing address

- Name
- Mailing address

If you would like more information about the types of wearable dialysis devices being developed, see the [*link to patient version of KHI roadmap*].

If you would like more information about kidney disease or treatment, see information about organizations that provide patient education and support here [*link*]. You can also talk to a clinical social worker or other member of your dialysis care team for questions or concerns about your own care.

Would you like to receive a summary of results from this survey?

Yes (please provide your email)

No

Would you like to help shape the future of dialysis treatments? Your contact information will be added to a directory for future contact by the Kidney Health Initiative. The Kidney Health Initiative will only contact you about future survey opportunities. Your survey answers remain anonymous.

Yes (please provide your email)

No

**¡Muchas gracias!**

Gracias por completar la encuesta. En este momento, se están fabricando las máquinas portátiles de diálisis descritos en esta encuesta y aún no están disponibles para los pacientes. Sus aportes a esta encuesta serán muy útiles para quienes fabrican estas máquinas. Su participación y las respuestas a la encuesta son confidenciales y no pueden relacionarse con usted.

Le enviaremos una tarjeta de regalo electrónica de \$35 dólares por correo electrónico. Por favor, proporcione su dirección de correo electrónico a continuación. Le enviaremos la tarjeta en 1-2 semanas después de completar la encuesta.

- Dirección de correo electrónico: \_\_\_\_\_

[For participants recruited through clinics only]

Le enviaremos una tarjeta de regalo electrónica de \$35 dólares por correo electrónico. Por favor, proporcione su dirección de correo electrónico a continuación. Le enviaremos la tarjeta en 1-2 semanas después de completar la encuesta.

- Dirección de correo electrónico: \_\_\_\_\_

Si prefiere recibir una tarjeta de regalo por correo regular, proporcione su nombre y dirección postal.

- Nombre completo
- Dirección de la calle
- Ciudad
- Estado/Provincia
- Código Postal

Si desea obtener más información sobre los tipos de máquinas portátiles de diálisis que se están fabricando, consulte el [*link to patient version of KHI map*].

Si desea obtener más información sobre la enfermedad renal o el tratamiento, consulte la información sobre las organizaciones que brindan educación y apoyo al paciente en el enlace a continuación [enlace]. También puede hablar con un trabajador social clínico u otro miembro de su equipo de atención de diálisis si tiene preguntas o inquietudes sobre su propia atención.

¿Desea recibir un resumen de los resultados de esta encuesta?

Sí (escriba su correo electrónico)

No

¿Le gustaría ayudar a mejorar el futuro de los tratamientos de diálisis? Su información de contacto se añadirá a un directorio para que la Iniciativa de Salud Renal se comunique con usted en el futuro. La Iniciativa de Salud Renal solo se comunicará con usted para informarle sobre futuras oportunidades de realizar encuestas. Sus respuestas se mantendrán anónimas.

Sí (ingrese su información de contacto)

- Nombre completo
- Correo electrónico
- Dirección de la calle
- Ciudad
- Estado/Provincia
- Código Postal
- Teléfono (opcional)

No