UNRAVELLING CURRENT SEXUAL CARE IN CHRONIC KIDNEY DISEASE: PERSPECTIVE OF SOCIAL WORKERS

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**SUMMARY**

**Background:** Fifty to eighty percent of patients suffering from chronic kidney disease (CKD) experience a form of sexual dysfunction (SD), even after renal transplantation. Despite this, inquiring about SD is often not included in the daily practice of renal care providers.

**Objectives:** This paper explores the perspectives of renal social workers regarding sexual care for patients and evaluates their practice, attitude towards responsibility and knowledge of SD.

**Design:** A cross-sectional study was conducted using a 41-item online survey.

**Participants:** Seventy-nine members of the Dutch Federation of Social Workers Nephrology.

**Results:** It was revealed that 60% of respondents discussed SD with a fifth of their patients. Frequency of discussion was associated with experience ($p = 0.049$), knowledge ($p = 0.001$), supplementary education ($p = 0.006$), and the availability of protocols on sexual care ($p = 0.007$). Main barriers towards discussing SD consisted of ‘culture and religion’ (51.9%), ‘language and ethnicity’ (49.4%), and ‘presence of a third person’ (45.6%). Sufficient knowledge of SD was present in 28% of respondents. The responsibility for discussion was 96% nephrologists and 81% social workers.

**Conclusion:** This study provides evidence that a part of Dutch nephrology social workers do not provide sexual care regularly, due to insufficient experience and sexual knowledge, absence of privacy and protocols and barriers based on cultural diversity. According to the respondents the responsibility for this aspect of care should be multidisciplinary. Recommendations include a need for further education on the topic, private opportunities to discuss SD and multidisciplinary guidelines on sexual care.

**KEY WORDS** Chronic kidney disease ● Practice patterns ● Sexual dysfunction ● Social workers

**BIO DATA**

Gaby F. van Ek, MD, PhD researcher, started studying Medicine at the Leiden University in 2008. In the last year of her medical school (2014), she started as a PhD candidate at the department of urology of the Leiden University Medical Centre (LUMC). The subject of her thesis is the evaluation of sexual, intimacy, fertility and relationship care in the department of nephrology. After obtaining her medical degree in 2015 she worked for 3 months as a urology resident in the Haga Hospital. In 2016 she returned to the department of urology of the LUMC and she started working full-time as a PhD-candidate under the supervision of Dr. H.W. Elzevier and Prof. Dr. R.C.M. Pelger.

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INTRODUCTION
Sexual dysfunction (SD) is the inability of a person to respond sexually or to experience sexual pleasure (Lewis et al. 2010). A person’s sexuality deteriorates on several levels: arousal, orgasm, sexual desire and pain disorders (Lewis et al. 2010; Berger et al. 2016). Multiple causes could underly the existence of SD, including chronic illnesses (Mväry 2007; Lou et al. 2017). Chronic kidney disease (CKD) is one of those illnesses causing deterioration of sexuality.

LITERATURE REVIEW
SD is a common problem in both male and female patients with CKD (Rathi & Ramachandran 2012). The aetiology of SD in CKD is often multifactorial and SD may occur throughout all stages of disease with effects worsening as renal function declines (Rathi & Ramachandran 2012; Palmer & Clegg 2017). Physical factors like hormone imbalances, uraemia and side effects of the medication play an important role in the development (Rathi & Ramachandran 2012; Palmer & Clegg 2017). Other CKD-related problems contributing to the existence of SD are changes in physical appearance causing a decline in body-image (Oyekcin et al. 2012; Palmer & Clegg 2017). This poor self-image is experienced by many patients undergoing dialysis, for instance due to the venous catheter for vascular access (Oyekcin et al. 2012; Palmer & Clegg 2017). Male patients may also encounter another body-image issue with 30% of them developing gynecomastia during dialysis (Palmer & Clegg 2017). In addition, patients with CKD are at risk of development of SD, because of the high prevalence of depression, anxiety and social withdrawal (Oyekcin et al. 2012; Theofilou 2012; Palmer & Clegg 2017).

In male CKD patients, 62–77% might suffer from erectile dysfunction and anejaculation, with the percentage dependant on the stage of renal disease (Rathi & Ramachandran 2012; Vecchio et al. 2012; Palmer & Clegg 2017). In female patients, 70% of them may encounter sexual issues during their course of disease. This could manifest in reduced lubrication and pain during intercourse (Rathi & Ramachandran 2012; Strippoli 2012; Palmer & Clegg 2017). Reduced libido is experienced by both male and female patients; the prevalence ranges from 48 to 56% in men up to 87–90% in women (Rathi & Ramachandran 2012; Palmer & Clegg 2017).

The best treatment for both SD and CKD is a donor kidney, as renal transplantation will improve patients’ energy level, sexual function and fertility (Filocamo et al. 2009; Wang et al. 2010; Schulz et al. 2013). Unfortunately, this does not apply to all patients, since SD often persists after transplantation. Approximately 50% of both male and female renal transplant recipients still experience SD, partially induced by the use of immunosuppressive medication (Muehrer 2009; Pertuz et al. 2014). Even after renal transplantation up to 70% of patients encounter disturbances in body-image that could negatively influence sexuality, including changes in body shape and unusual hair growth (Muehrer 2009).

Several care providers contribute to the treatment and counseling of patients with CKD, including nephrologists, dialysis nurses, social workers, and transplant surgeons. Some are present during the whole patient journey, others only in a specific stage of disease. In the Netherlands, social workers specialized in nephrology support their patients throughout the whole course of disease; starting at end-stage kidney disease and continuing even after renal transplantation. Frequency of consultation can differ from three times per year up to once every month, depending on the stage of disease and patients’ need.

Providing adequate health care for patients depends on multiple factors, including the discussion of SD. Unfortunately, skipping the discussion of SD with patients during consultation is a tendency that exists amongst most renal care providers. Only a few studies are published about sexual care as a part of renal health care and results exposed the undervaluation of SD by renal care providers (Ho & Fernandez 2006; Weisbord et al. 2007; Burnett et al. 2009). Burnett et al. (2009) showed that Canadian social workers specialized in nephrology did not inquire about patients’ sexuality due to lack of knowledge, the lack of a private setting for such a discussion, personal discomfort and because patients did not raise the topic themselves (Burnett et al. 2009). Until recently, no similar research was performed in the Netherlands.

AIM OF STUDY
The aim of this cross-sectional study was to explore the perspective of Dutch social workers working in nephrology on current sexual care for patients with CKD and how this part of renal care is structured within their departments. This survey focused on current practice patterns, attitudes, professional responsibility and barriers of social workers towards discussing SD. Furthermore, the survey focused on social workers’ level of knowledge about SD and received sexual education during social work studies.
METHODS

STUDY DESIGN
This cross-sectional survey was conducted between September and October of 2013 using an online questionnaire. The sample consisted of all practicing Dutch Nephrology social workers (N = 129) who were members of the Dutch Federation of Social Workers Nephrology (VMWN). All members were certified social workers with a degree of an accredited school of social work, following four years of education. E-mail addresses of the social workers were obtained from the VMWN and an invitation, including an URL link, was send by e-mail to complete the online questionnaire. In the Netherlands, no formal ethical approval was needed to perform this study since no patients or interventions were involved. Informed consent was obtained electronically from all individual participants included in the study.

INSTRUMENT DESIGN AND DEVELOPMENT
The authors composed the content of the questionnaire; structure and design were derived from questionnaires used in previous studies on sexuality and health care providers (Nicolai et al. 2013; Krouwel et al. 2015; Van Ek et al. 2015; Van Ek Gf et al. 2017). These previously used questionnaires were developed by a team of experts, including a urologist-sexologist, and shown to be reliable instruments. General items relating to all type of care providers were reused, other questions were altered to the specific situation of social workers specialised in nephrology. These alterations were made based on issues described in the literature and additional themes identified by the authors. The survey was pilot tested by nine social workers; eight were working in the Westfries hospital (Westfriesgasthuis), one in the VU University Medical Centre. As a result of the pilot study, Dianet (an organisation specialising in haemodialysis at home) was added as an option to the list of clinics in the demographic section and respondents were given the opportunity to list additional workshops or education regarding sexual health that they received after becoming a licensed social worker.

The digital questionnaire was distributed by an online platform called Easion Survey (Parantion).

SURVEY AND PROCEDURE
The 41-item questionnaire contained multiple choice and open-ended questions. The first seven items addressed demographic characteristics. The focus of the following questions was aimed at

1) current practice regarding sexual care (19 items)
2) barriers towards providing sexual care (1 item)
3) self-reported level of knowledge and received education on SD during social workers studies (4 items)
4) the need for training on SD (1 item)
5) social workers’ perspective on who should be responsible for discussing SD with patients (6 items) and
6) how sexual care is structured and embedded in the nephrology departments of social workers (4 items).

Ninety-seven non-respondents (75.1%) received a reminder email, including URL link, one week after the initial mailing and a second reminder was send after two weeks to 68 social workers (52.7%). Three months before the survey started, an oral presentation at a regional conference for social workers nephrology was held to raise awareness of the study and to emphasise the importance of participation. Furthermore, in an attempt to increase the response rate, six copies of the book ‘Healthcare basics for sexuality’ (Zorgbasics seksualiteit) were raffled among participants.

ANALYSIS
Data analyses were performed by using IBM SPSS statistics 23 (SPSS Inc., Chicago, IL, USA). Demographic information and answers to the survey were analysed using descriptive statistics. With the use of Cochran-Armitage Trend Test, bivariate associations were calculated between categorical variables with two or more categories. Outcomes were considered statistically significant if the two-sided p-values were < 0.05.

RESULTS

SURVEY PARTICIPANTS
Eighty-four of the 129 social workers in nephrology participated in the online survey, resulting in a response rate of 65.1%. Five surveys were excluded for non-completion. A total of 79 questionnaires were analysed (61.2%). A list of respondents’ characteristics is presented in Table 1.

DISCUSSION OF SD
Half of the social workers (n = 41, 51.9%) experienced that patients (almost) never addressed sexual concerns spontaneously. Thirty-five respondents (44.3%) said that less than 50% of their patients spontaneously addressed their sexual concerns. In the daily practice of two respondents (2.5%), 50% of the patients expressed their concerns spontaneously and one respondent (1.3%) stated this occurred in more than 50% of the cases. Several questions focused on the discussion of SD by
social workers working in nephrology. These questions and answers of respondents are listed in Table 2. If social workers had more years of experience (Linear-by-Linear Association, p = 0.03) or if they received additional workshop of education regarding sexuality after they become a certified social worker (Linear-by-Linear Association, p = 0.006), they were more likely to discuss SD with a new patient.

**PRACTICE PATTERNS**

Several questions were addressed regarding respondents’ practice patterns in the past year. The results are listed in Table 3. Social workers with more experience discussed sexual health with a higher percentage of their patients (Linear-by-Linear Association, p = 0.049). Eleven social workers (13.9%) did not provide information or sexual health counselling to any of their patients in the past year and 50.6% (n = 40) referred up to 20% of their patients to a physician specialising in SD.

**BARRIERS**

The survey contained a list of potential barriers that could prevent social workers from discussing SD with patients. Respondents were asked to which extent they agreed or disagreed with each of the barriers listed. Answers are showed in Table 4. Barriers mostly agreed on by the social workers were ‘barriers based on culture or religion’ (51.9%), ‘barriers based on language and ethnicity’ (49.4%), and ‘presence of a third person’ (45.6%). Social workers disagreed the most with the barriers ‘SD is not relevant in CKD’ (92.4%) and ‘My colleagues find it inappropriate when I discuss SD’ (94.9%).

**KNOWLEDGE AND TRAINING**

Respondents were asked to rate their current knowledge about two subjects: a) knowledge of SD, as a consequence of CKD and b) knowledge of SD as a consequence of treatment for CKD. Another question was aimed at indicating the amount of attention paid to SD during social workers’ education. Respondents’ answers are listed in Table 5. The more knowledge nephrology social workers were noted to possess, the more they inquired after sexuality in their current practice and the more likely they were to refer their patients for sexual counselling. The p-values ranged from 0.002 up to 0.036 (Linear-by-Linear Association). To the question ‘Are you in need of extending your knowledge on sexual dysfunction?’, 69.6% (n = 55) of the social workers answered affirmatively.

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Mean: 46.91 (SD: 9.99)</td>
<td>79 (100.0)</td>
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<tr>
<th>Gender</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Female</td>
<td>63 (79.7)</td>
</tr>
<tr>
<td>Male</td>
<td>16 (20.3)</td>
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<tr>
<th>Department(s) of employment</th>
<th>n (%)</th>
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<tr>
<td>Pre-dialysis</td>
<td>63 (79.7)</td>
</tr>
<tr>
<td>Dialysis</td>
<td>75 (94.9)</td>
</tr>
<tr>
<td>Transplantation</td>
<td>15 (19.0)</td>
</tr>
<tr>
<td>Other</td>
<td>15 (19.0)</td>
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<tr>
<th>Area(s) of expertise</th>
<th>n (%)</th>
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<tr>
<td>Pre-dialysis</td>
<td>69 (86.1)</td>
</tr>
<tr>
<td>Haemodialysis</td>
<td>76 (96.2)</td>
</tr>
<tr>
<td>Peritoneal dialysis</td>
<td>67 (84.8)</td>
</tr>
<tr>
<td>Nocturnal centre dialysis</td>
<td>32 (40.5)</td>
</tr>
<tr>
<td>Haemodialysis at home</td>
<td>40 (50.6)</td>
</tr>
<tr>
<td>Transplantation</td>
<td>33 (41.8)</td>
</tr>
<tr>
<td>Other</td>
<td>8 (10.1)</td>
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<table>
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<tr>
<th>Work experience (years)</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>&lt;1</td>
<td>5 (6.3)</td>
</tr>
<tr>
<td>1–2</td>
<td>10 (12.7)</td>
</tr>
<tr>
<td>3–5</td>
<td>29 (36.7)</td>
</tr>
<tr>
<td>6–10</td>
<td>23 (29.1)</td>
</tr>
<tr>
<td>11–15</td>
<td>6 (7.6)</td>
</tr>
<tr>
<td>&gt;15</td>
<td>6 (7.6)</td>
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<table>
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<tr>
<th>Clinical setting</th>
<th>n (%)</th>
</tr>
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<tbody>
<tr>
<td>Tertiary referral hospital (or university hospital)</td>
<td>15 (19.0)</td>
</tr>
<tr>
<td>General teaching hospital</td>
<td>31 (39.2)</td>
</tr>
<tr>
<td>District general hospital</td>
<td>25 (31.6)</td>
</tr>
<tr>
<td>Dialysis clinic, outside the hospital</td>
<td>20 (25.3)</td>
</tr>
<tr>
<td>Dialysis at home</td>
<td>2 (2.5)</td>
</tr>
<tr>
<td>Other: Kidney centre</td>
<td>1 (1.3)</td>
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<table>
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<tr>
<th>Received supplementary workshops/education regarding sexual health after becoming a licensed social worker</th>
<th>n (%)</th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
<td>32 (40.5)</td>
</tr>
<tr>
<td>No</td>
<td>47 (59.5)</td>
</tr>
</tbody>
</table>

Table 1: Respondent characteristics (n = 79).

<table>
<thead>
<tr>
<th>How often do you discuss SD:</th>
<th>(Almost) never</th>
<th>&lt;50% of the cases</th>
<th>50% of the cases</th>
<th>&gt;50% of the cases</th>
<th>(almost) always</th>
</tr>
</thead>
<tbody>
<tr>
<td>With a new patient</td>
<td>22 (27.8)</td>
<td>23 (29.1)</td>
<td>12 (15.2)</td>
<td>11 (13.9)</td>
<td>11 (13.9)</td>
</tr>
<tr>
<td>During follow-up</td>
<td>27 (34.2)</td>
<td>34 (43.0)</td>
<td>6 (7.6)</td>
<td>4 (5.1)</td>
<td>8 (10.1)</td>
</tr>
<tr>
<td>In presence of the partner</td>
<td>28 (35.4)</td>
<td>26 (32.9)</td>
<td>12 (15.2)</td>
<td>13 (16.5)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Table 2: Discussing sexual dysfunction.

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ORGANIZATION AND RESPONSIBILITY

Protocols about the topic sexual care were available in less than half of social workers’ departments (n = 33, 41.8%). Half of the respondents (n = 40) worked at a department where no protocols existed and six social workers (7.6%) were unaware of such protocols within their departments. If social workers were aware of protocols regarding sexual care, they discussed this subject more often with their new patients (Linear-by-Linear Association, p < 0.007). Figure 1 illustrates all answers to the question ‘Who do you think is responsible for the discussion of SD, as a consequence of patients’ disease or treatment?’. Ninety-six percent (n = 76) of the respondents indicated the nephrologist should be responsible. Sixty-four social workers (81.0%) thought social workers should be responsible for this themselves.

DISCUSSION

This study provides insight into the current practice of Dutch nephrology social workers with regards to sexual care for patients with CKD. Results showed that the majority do not discuss SD consistently during consultation. A recent study among Canadian nephrology social workers had comparable results and the authors posed that similar situations might be present in other countries as well. Their findings showed that 52.4% of the social workers initiated discussing SD at some point during treatment, but none of their respondents did this...
routinely (Burnett et al. 2009). In the current study, only a fourth of the Dutch social workers, often those with more years of experience, discussed sexual health on a regular basis. It is possible that the skills, knowledge, and confidence that social workers acquired during their years of practice enabled them to discuss sexuality with their patients, or it might be that they are more aware of patients’ (unspoken) concerns about SD. In practice, patients rarely express those concerns spontaneously since they are afraid care providers would not take them seriously (Marwick 1999; Althof et al. 2013).

Culture, religion, language, and ethnicity were the most important frequently cited barriers for nephrology social workers to avoid discussing SD. Skills, knowledge, and attitudes necessary to provide health care in a multi-cultural population can be defined as cultural competence. Due to increasing diversity in the community, among both patients and care providers, difficulties with cultural competence are experienced often throughout several medical departments (Kai et al. 2007; Fleckman et al. 2015). Although precise information on cultural competence in the context of providing sexual care is missing, one could imagine that care providers would even need more competence due to the sensitive subjects that need to be discussed. Another important barrier hindering social workers in bringing up SD is the absence of a private setting to discuss this subject. Burnett et al. (2009) showed similar data figures among Canadian nephrology social workers as they stated ‘lack of privacy’ to be the number one reason not to initiate a discussion around sexuality with their patients (Burnett et al. 2009). These findings may be partially explained by the fact that patients undergoing haemodialysis often have the consultation with their social worker on the haemodialysis unit. In this haemodialysis unit, they receive dialysis together with 10–15 other patients, so most of the time privacy is absent.

Outcomes of the present study underline social workers’ sense of responsibility for the discussion of sexual health with patients. However, most respondents thought the responsibility should be multidisciplinary. Previous results from our research group showed this opinion is shared by nephrologists (Van EK et al. 2015). Unfortunately, clear and multidisciplinary protocols concerning the format of sexual care for patients with CKD are absent in most nephrology departments, while findings in this study indicate that protocols would be beneficial to the discussion of SD (Van EK et al. 2015; Van Ek Gf et al. 2017).

In order to achieve improvement, this study underlined the importance of self-reported knowledge and adequate education in enabling social workers to provide sexual care. Unfortunately, sufficient knowledge on patients’ sexuality is not self-evident (Burnett et al. 2009). This might be a result of insufficient education. Although several social workers received

<table>
<thead>
<tr>
<th>How much knowledge do you have on:</th>
<th>None at all n (%)</th>
<th>Not much n (%)</th>
<th>Some n (%)</th>
<th>Sufficient n (%)</th>
<th>A lot n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD as a consequence of CKD</td>
<td>1 (1.3)</td>
<td>14 (17.7)</td>
<td>40 (50.6)</td>
<td>22 (27.8)</td>
<td>2 (2.5)</td>
</tr>
<tr>
<td>SD as a consequence of treatment for CKD</td>
<td>1 (1.3)</td>
<td>20 (25.3)</td>
<td>37 (46.8)</td>
<td>19 (24.1)</td>
<td>2 (2.5)</td>
</tr>
<tr>
<td>To what extent do you agree with the following statement?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sufficient attention was paid to SD during my social work</td>
<td>3 (1.8)</td>
<td>4 (5.1)</td>
<td>24 (30.4)</td>
<td>33 (41.8)</td>
<td>15 (19.0)</td>
</tr>
</tbody>
</table>

Table 5: Level of knowledge and education.

SD: sexual dysfunction. CKD: Chronic Kidney Disease.

Figure 1: Who do you think is responsible for the discussion of sexual dysfunction as a consequence of patients’ disease or treatment?
supplementary sexual health workshops after obtaining their social work degree, shortcomings in the current educational system for future social workers regarding sexual education were identified. Insufficient attention to sexuality during training is not an issue confined to the renal social workers, as omissions in sexual education can occur throughout all health care departments in nephrology (Ho & Fernandez 2006; Van EK et al. 2015; Van Ek Gf et al. 2017).

**STRENGTHS AND LIMITATIONS**
This study was one of the first to examine sexual care provided by social workers working in nephrology and had a high response rate compared to another online questionnaire among nephrology social workers (65.1 vs. 37%) (Burnett et al. 2009). However, non-response bias may still have occurred as the remaining 35% of Dutch nephrology social workers may have a different perspective on sexual care in CKD. A non-validated questionnaire was used to perform this study as no validated questionnaires were available that assessed the specific study aims. Furthermore, as a consequence of the self-reported character of the survey, over- or underestimation might have occurred as social workers may have given socially desirable answers leading to response bias.

**CONCLUSION**
The majority of the Dutch nephrology social workers do not consistently provide sexual care for their patients due to insufficient knowledge, the absence of privacy during consultations, the lack of protocols within their departments and barriers based on cultural diversity. A sense of responsibility is present in this group of renal care providers, however they feel this responsibility should be multidisciplinary.

**IMPlications FOR Practice**
In order to enhance current sexual care provided by social workers in nephrology, the following changes are recommended:

1) **The improvement of knowledge on cultural diversity:** Introducing education on cultural differences in the context of providing health care, especially sexual care, could improve competence among nephrology social workers (Althof et al. 2013). As a result, existing barriers might diminish (Kai et al. 2007; Fleckman et al. 2015)

2) **The improvement of knowledge on sexuality in CKD patients:** By improving current education on SD and providing supplementary training, knowledge on SD and confidence of social workers will improve; a need pointed out by the majority of the respondents in this study as well as by Canadian nephrology social workers (Burnett et al. 2009)

3) **The facilitation of a private appointment to discuss sexual health:** It might be important to facilitate a scheduled consultation where privacy and confidentially are assured. Such an environment could lead to trust, comfort, and openness for both social worker and patient and therefore facilitate the discussion of sexuality and sexual concerns (Althof et al. 2013).

4) **The development of multidisciplinary protocols:** These protocols should be available in all renal care departments so sexual care for patients with CKD will be provided in a multidisciplinary manner.

**ACKNOWLEDGEMENTS**
The authors thank all Dutch social workers in nephrology who took the time to fill out the questionnaire. Linguistic supervision was performed by Emma Horton, MD. This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

**CONFLICT OF INTEREST**
No conflict of interest has been declared by the author(s).

**AUTHOR CONTRIBUTIONS**
GE: (1) the conception and design of the study, acquisition of data, and analysis and interpretation of data; (2) revising it critically for important intellectual content; and (3) final approval of the version to be submitted. DK: (1) analysis and interpretation of data; (2) drafting the article; and (3) final approval of the version to be submitted. EK: (1) analysis and interpretation of data; (2) revising it critically for important intellectual content; and (3) final approval of the version to be submitted. MN: (1) analysis and interpretation of data; (2) revising it critically for important intellectual content; and (3) final approval of the version to be submitted. HW: (1) the conception and design of the study, acquisition of data, and analysis and interpretation of data; (2) revising it critically for important intellectual content; and (3) final approval of the version to be submitted. HP: (1) analysis and interpretation of data; (2) revising it critically for important intellectual content; and (3) final approval of the version to be submitted. RP: (1) the conception and design of the study; (2) revising it critically for important intellectual content; and (3) final approval of the version to be submitted. BO: (1) the
conception and design of the study, acquisition of data, and analysis and interpretation of data; (2) revising it critically for important intellectual content; and (3) final approval of the version to be submitted.

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