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Improving cervical cancer screening participation by introducing HPV vaginal self-sampling to women living with HIV in Denmark– a pilot study

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Abstract

Background Cervical cancer, despite being largely preventable through vaccination and screening, continues to pose a significant global health challenge. Women living with HIV (WLWH) are at a six-fold higher risk of developing cervical cancer, primarily due to persistent infection with high-risk HPV (hrHPV). While effective screening methods have the potential to reduce this risk, WLWH remain inadequately screened. The aims of this pilot study were fourfold: To estimate the proportion of WLWH who are not screened according to WHO guidelines; to establish the proportion of WLWH who accepted the self-sampling offer; to estimate the hrHPV DNA prevalence; and to estimate the compliance to follow-up among women with a hrHPV-positive vaginal self-sample.

Methods This single-centre, pilot study was conducted from February to May 2022 at the Department of Infectious Diseases, Aarhus University Hospital, Central Denmark Region. Eligible women were contacted by phone and invited to participate. Participants were provided with a self-sampling kit (Evalyn® Brush) and detailed instructions. The collected samples were analysed for hrHPV DNA using the COBAS® 4800 assay. Demographic, clinical, and screening history data were obtained from medical records and the Danish Pathology Databank.

Results Of the 100 eligible participants, 50% ($n = 50$) accepted the offer of self-sampling, and 80% ($n = 40/50$) returned their samples for analysis. The prevalence of hrHPV among these women was 25% ($n = 10/40$). Follow-up compliance among hrHPV-positive women was 40% ($n = 4/10$). The analysis revealed that 41% ($n = 41/100$) of WLWH had not been screened in accordance with WHO guidelines, and 39% ($n = 16/41$) of the women had never undergone screening. No significant differences were observed in demographic or clinical characteristics between participants and non-participants.

Conclusions Vaginal hrHPV self-sampling was acceptable and feasible for WLWH, with high return rates but suboptimal follow-up compliance. Enhancing participation and adherence is crucial for effective cervical cancer prevention. Larger studies are needed to validate these findings and optimize screening strategies.

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Trial registration The Central Denmark Region Committee on Health Research Ethics deemed this study as a quality improvement study on the 9th of November 2021 (request approval j.no: 204/1-10-72-274-21). Clinical trial number: Not applicable.

Keywords Cervical cancer screening, Women living with HIV, High risk human papillomavirus, HPV self-sampling

Background

Despite cervical cancer (CC) is preventable through vaccination, screening and preventive treatment of precursor lesions, it remains the fourth most common cancer in women worldwide with 661,021 cases and almost 350,000 deaths in 2022 [1]. Almost all CC cases and its pre-cancerous lesions are attributed to persistent infection with high risk human papilloma virus (hrHPV) [2]. Screening programs allow pre-cancerous lesions to be detected and treated and have resulted in reduced incidence and mortality of the disease [2].

Women living with HIV (WLWH) are at greater risk of having persistent hrHPV infection and have a six-fold higher risk of developing CC compared to the background population [2, 3]. The Danish Shade cohort study, found a hrHPV prevalence of 28% among WLWH in Denmark [4] while reports on the hrHPV prevalence in low-income countries showed an even higher prevalence (range: 40.6–53.6%) among WLWH [5, 6]. Thus, screening for CC is of particular importance among WLWH. Nevertheless, a large proportion of WLWH are either immigrants or belong to lower socio-economic groups, both of which are acknowledged risk factors linked to being non-screened or under-screened compared to the background population [7, 8]. Interventions aimed at increasing participation in CC screening among WLWH are therefore urgently needed.

Since 2021, WHO has recommended CC screening among WLWH every third to fifth year when using HPV DNA detection as primary screening test and every third year when using visual inspection with acetic acid (VIA) or cytology-based screening [2]. This recommendation relies on evidence that attest the superior sensitivity of HPV-based screening to detect high-grade cervical intraepithelial neoplasia (CIN grade 2 or worse, CIN2+) and cancer as compared to VIA and cytology-based screening [2]. In contrast to WHO guidelines, The European AIDS Clinical Society (EACS) guidelines recommend annual CC screening using cytology-based screening for WLWH, and these are the guidelines followed in Denmark [9]. However, several countries are currently transitioning from cytology-based to HPV-based screening, which allows women to collect cervico-vaginal material themselves in their own home or at a clinic using a device and return it for hrHPV testing at the laboratory (HPV self-sampling). HPV self-sampling has proven accurate [10, 11], highly acceptable [12–14], and has improved CC screening participation in both

low-income and high-income countries including Denmark, especially among under-screened women [8, 15, 16].

HPV self-sampling participation rates found in previous studies conducted in high-income countries vary and depend on the invitation strategy and accessibility of self-sampling kits. A recent study from UK, assessing the feasibility and acceptability of offering HPV self-sampling to WLWH, found a participation rate of 88% [17].

Our pilot study evaluated for the first time the feasibility of offering home-based hrHPV self-sampling as a novel, non-invasive screening method for CC among under-screened WLWH in a Scandinavian country. The aims of this study were fourfold: To estimate the proportion of WLWH who are not screened according to WHO guidelines; to establish the proportion of WLWH who accepted the self-sampling offer; to estimate the hrHPV DNA prevalence; and to estimate the compliance to follow-up among women with a hrHPV positive vaginal self-sample.

Methods

Setting

The organized Danish CC screening program targets women aged 23–64 years. The women receive an invitation to attend screening at their general practitioner (GP) every third or fifth year depending on age. Participation and eventual diagnostic follow-up and treatment are free of charge. During this study period, women aged 23–29 were screened with cytology, whereas women aged 30–59 years underwent HPV-based screening if born on uneven dates and cytology-based screening if born on even dates. Women aged 60–64 have an HPV-DNA exit test. Non-participants receive two screening reminders. In the Central Denmark Region and three additional regions, women are in the second reminder also offered to opt-in for vaginal self-sampling (Evalyn brush device). This current study took place in the Central Denmark Region, where all cervical cytology samples are routinely handled and analysed by the Department of Pathology, Randers Regional hospital.

Design and study population

This preliminary single centre pilot study was conducted between February and May 2022 at the Department of Infectious Diseases at Aarhus University Hospital, Central Denmark Region, where HIV treatment and care is provided for individuals living with HIV at an outpatient

clinic. Women living with HIV between age 23–64 years were eligible for study inclusion. Exclusion criteria were pregnancy, hysterectomy, non-Danish-speaking women (because user instructions were in Danish), and inability to follow the instructions. Women who were screened for CC within the last 12 months prior to February 1st, 2022, were excluded because we aimed to target under-screened women.

Study intervention

Eligible women were contacted by phone by an HIV counsellor from the department. Women who did not respond to multiple phone calls (at least three), received a text message with information about the study and were offered to participate. Information, either verbal (phone call) or text (text message), consisted of brief background information on hrHPV, CC and CC screening recommendations, followed by an introduction to this study. Women who agreed to participate received a package by mail containing a vaginal self-sampling kit including the dry Evalyn® Brush (Rovers Medical Devices, B.V, Oss, Netherlands), written and picture-based user instructions, and a pre-paid return envelope addressed to Randers Pathology Department. Women who did not return their self-sample within one month received one reminder on text message. Upon arrival at the laboratory, the dry brush head was rinsed in 10 mL SurePath medium (BD Diagnostics, Burlington, USA), vortexed for 15–30 s, and stored at 4°C until further hrHPV testing. A 1 mL aliquot of the vaginal sample was used as the starting point for the Cobas®4800 HPV DNA testing (Roche Diagnostics, Switzerland), which provides results for HPV16, HPV18 and pooled detection of 12 other HPV types (HPV31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) [18]. Women with a hrHPV positive self-sample (regardless of genotype) were phoned by a doctor from The Infectious Disease clinic and recommended to contact their GP for a cervical cytology sample to evaluate the need for the referral for colposcopy. Thereafter, the women were followed up according to national guidelines [19]. A copy of the test result was sent to the GP of each participant.

Data sources

Information about age, ethnicity, time since HIV diagnosis, quantitative HIV RNA levels, and current pregnancy were collected from the women's medical journals. We categorized participants ethnicity based on self-identified ethnicity reported in the medical journal, using the groupings Caucasian and non-Caucasian.

Data on CC screening history, hysterectomy, hrHPV results of the vaginal self-collected samples as well as results of any triage and/or histological follow-up was retrieved from the nationwide Danish Pathology

Databank [20]. The number of women who participated (performed a vaginal self-collected sample and send it for successful analysis) were evaluated six months after the study started. Compliance to follow-up at the GP was evaluated after one year. The collection of data and subsequent follow up was possible due to a unique Civil Personal Registration (CPR) number which is assigned to each Danish citizen upon birth or to residents upon immigration. This number is linked to the individual's medical journal and the pathology bank, enabling continuous data management.

Statistics

Baseline characteristics of study participants and non-participants were reported using descriptive statistics (n and proportions) and for continuous data, medians, and interquartile ranges (IQR) were calculated.

The chi-2 test was used to test for differences in categorical variables between participants and non-participants, differences in proportions were tested with two-sample test, and the Mann-Whitney U-test was used as a test of population medians. The association between CC screening history and the hrHPV test result was graphed as a boxplot.

P-values < 0.05 were considered statistically significant. Data was entered and stored in RedCap [21, 22]. Statistical analyses were performed using STATA version 17 and GraphPad version 10.

Ethical approval

The Central Denmark Region Committee on Health Research Ethics deemed this study as a quality improvement study (request approval j.no: 204/1-10-72-274-21). Thus, written informed consent was therefore not required. However, participating women gave verbal informed consent when they were contacted by phone.

Results

Inclusion of patients

From a total of 199 WLWH followed in the outpatient clinic, 100 women (50.3%) were eligible for inclusion (Fig. 1). Eleven (11%) women did not wish to participate, while 39 (39%) women were unreachable by phone and text message. The remaining 50 women (50.0%) accepted to receive the hrHPV self-sampling kit of whom 40 (80%) returned the self-sample for HPV testing.

Demographics, clinical characteristics, and screening history

Baseline demographics and clinical characteristics of the study cohort are shown in Table 1.

The women who received the hrHPV self-sampling kit but did not return it for analysis (*n* = 10) was pooled together with women who did not wish to participate or

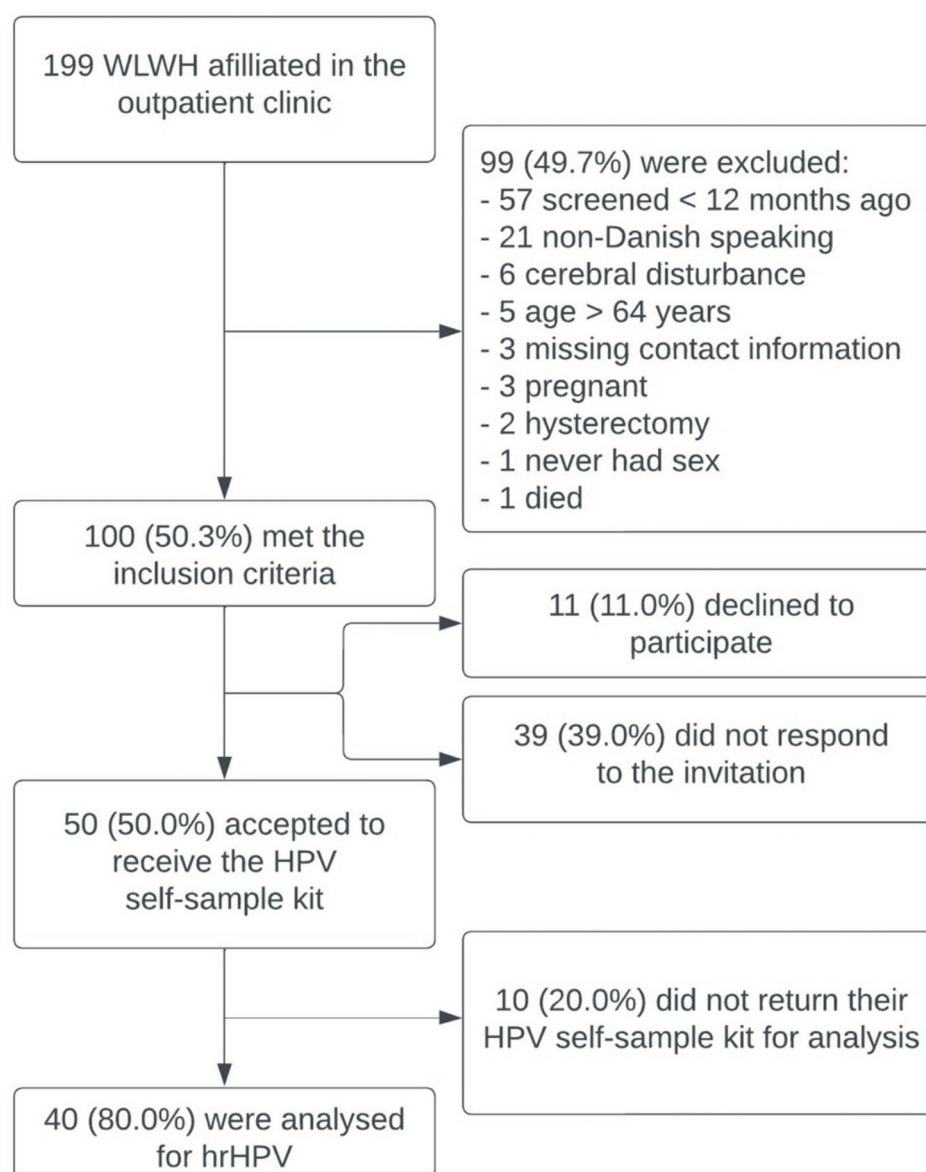


Fig. 1 Flowchart of inclusion

did not respond to the invitation as these groups did not differ in terms of age distribution, time since HIV diagnosis, ethnicity, CC screening history, and quantitative HIV RNA levels (data not tabulated).

We found no difference between women screened by hrHPV self-sampling (participants) and non-participants with regards to age (51.5 vs. 49.0, respectively, $p_{\text{mwhit}}=0.5$), time since HIV diagnosis (15.0 vs. 16.0 years, respectively, $p_{\text{mwhit}}=0.8$), ethnicity ($n=15.0$ vs. $n=18.0$, respectively, $p_{\text{chi}}=0.8$), and quantitative HIV RNA levels ($p_{\text{chi}}=0.6$) (Table 1). At the time of enrollment in the study, all women were receiving antiretroviral therapy (ART), except for one woman (who did not accept to receive the self-sampling kit).

Prior to the study, 59% ($n=59/100$) of all eligible women (both participants and non-participants) had been CC screened according to WHO recommendations (within 3–5 years) (Table 1). Of the 100 women fitting the inclusion criteria, 41% ($n=41/100$) had not previously been screened according to WHO recommendations (Table 1), of whom 61% ($n=25/41$) had not been screened within the last five years and 16 (39%, $n=16/41$) were never screened. There was no difference between women screened by hrHPV self-sampling (participants) and non-participating women ($p_{\text{chi}}=0.3$) with regards to prior screening participation.

Table 1 Demographics and clinical characteristics

Variables	hrHPV self-test (participants)	No hrHPV self-test (non-participants)	p-value
	n = 40	n = 60	
Age (years) at inclusion (median) (IQR)	51.5 (42.3–56.0)	49.0 (44.3–55.0)	0.5
Age range at inclusion, n (%)			0.4
23–40 years	7 (17.5)	7 (11.7)	
41–64 years	33 (82.5)	53 (88.3)	
Time (years) since HIV diagnosis, (median) (IQR)	15 (12.0–24.0)	16 (11.0–21.0)	0.8
Time range since HIV diagnosis, n (%)			0.6
0–10 years	7 (17.5)	14 (23.3)	
11–20 years	20 (50.0)	31 (51.7)	
> 20 years	13 (32.5)	15 (25.0)	
Caucasians (ethnicity), n (%)	15 (37.5)	18 (30.0)	0.8
Time (years) since last CC screening, (median) (IQR)	3 (2.0–6.0)	4 (2.0–8.0)	0.4
Time range since last CC screening, n (%)			0.9
3–5 years	24 (60.0)	35 (58.3)	
> 5 years	9 (22.5)	16 (26.7)	
Never screened	7 (17.5)	9 (15.0)	
Quantitative HIV RNA range, n (%)			0.6
Undetectable	35 (87.5)	54 (90)	
< 50 copies/ml	3 (7.5)	5 (8.3)	
> 50 copies/ml	2 (5.0)	1 (2.7)	

did not respond to the invitation as these groups did not differ in terms of age distribution, time since HIV diagnosis, ethnicity, CC screening history, and quantitative HIV RNA levels (data not tabulated)

hrHPV DNA prevalence among WLWH

The hrHPV prevalence was 25%, (95% CI: 12.7–41.2%, $n=10/40$). Of the 10 hrHPV-positive samples, HPV16 was found in 30% (95% CI: 6.7–65.2%, $n=3/10$) and HPV other types in 70% (95% CI: 34.8–93.3%, $n=7/10$). The compliance to follow-up at the GP was 40%, 95% CI: 12.2–73.7%, $n=4/10$. Two of these women were diagnosed with CIN2 and the remaining two women had normal cytology results without histology follow-up.

Association between CC screening history and HrHPV test result

The association between the time since last CC screening and having a positive or negative hrHPV vaginal self-collected sample is visualized in Fig. 2. Women who had never been screened are not shown in the figure. The median time since last CC screening test was significantly higher among women having a hrHPV-positive vaginal

sample (median: 7 years, IQR: 2.0–13 years) than among women with a hrHPV-negative vaginal sample (median: 3 years, IQR: 2.0–5.3 years, $p_{\text{mwhit}}=0.02$).

Discussion

Main findings

This study found that 41% of WLWH aged 23–64, followed at a single Infectious Disease Clinic in Denmark, had not undergone CC screened as recommended by WHO. Among these women, 16% had no prior screening record in the Danish Pathology Databank. Half (50%) of eligible participants accepted home-based hrHPV self-sampling, with an 80% return rate and a 25% hrHPV prevalence. Notably, 17.5% of those who returned samples had no prior screening history. Compliance to follow-up at the GP among those testing hrHPV positive was low (40%).

Strengths and limitations

A key strength to this study is the use of a thoroughly validated vaginal self-sampling device with high acceptability [8]. Additionally, systematic data collection through the Danish Pathology Bank minimized loss to follow-up.

However, several limitations should be considered. The small sample size limits the generalizability and statistical power of our findings, while the lack of a control group prevents direct causal inference.

Furthermore, the exclusion of non-Danish speakers reduced the representativeness of the study. Addressing this issue would require translating study materials in multiple languages, which could enhance broader implementation.

Another limitation is the underrepresentation of younger women (25–40 years), restricting insights into hrHPV prevalence in this group. Future research should aim for a more balanced age group representation to fully capture the dynamics across different age groups of WLWH.

Interpretation and comparison with previous research

Our findings highlight the need for improved CC screening among WLWH, given that 41% (Table 1) of these women remain under screened, and exhibit high prevalence of hrHPV. Self-sampling proved to be an effective strategy, particular in reaching under screened women.

However, it is important to note that our study excluded women screened within the last year (57 WLWH) making the 41% under-screening estimate not fully generalizable to all WLWH. When including those adhering to annual screening, the under-screening rate was lower, at approximately 26%.

The 80% return rate for HPV self-sampling in our study is comparable to a UK study reporting 88% participation when self-sampling was offered in person [17]. However,

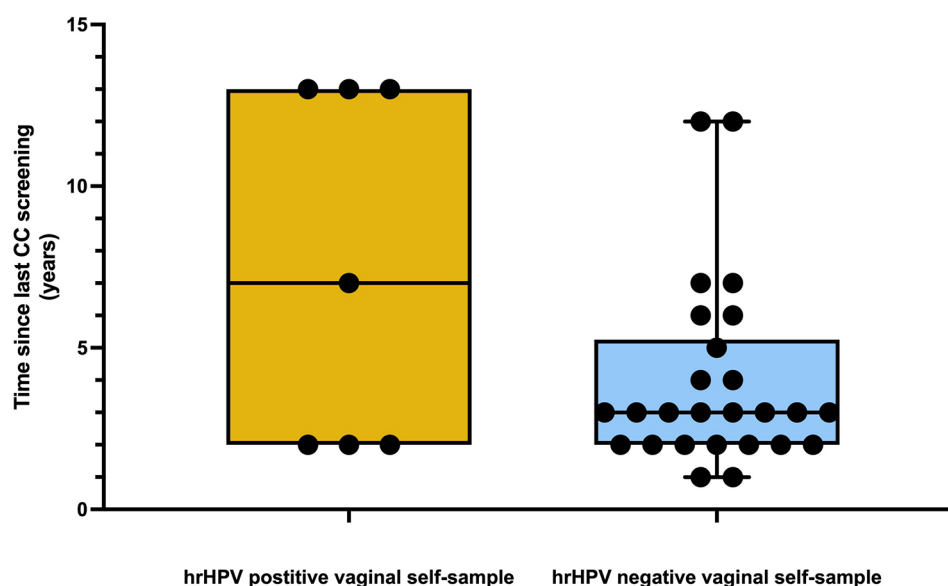


Fig. 2 Association between CC screening history and hrHPV test result

39% of invited women in our study did not respond to the invitation (phone call or text message). This suggests offering self-sampling during annual HIV check-ups might enhance participation, particular among immigrants and socioeconomically disadvantaged groups. This approach could also facilitate inclusion of non-Danish speakers through direct guidance in English or interpreter services.

Urine-based hrHPV testing represents another potential strategy to improve CC screening. This non-invasive method has demonstrated high acceptability and feasibility [23–28] and may be particular beneficial for women reluctant to undergo invasive procedures [25, 26, 29].

With a 25% hrHPV prevalence among WLWH, our findings align with a prior Danish study that reported a 28% prevalence using clinician-collected cervical samples [4]. The effectiveness of hrHPV self-sampling relies on a strong adherence to subsequent follow-up procedures among those testing positive. However, the follow-up compliance in our study was only 40%, in contrast to the 90.7% follow-up compliance reported in a Danish study on hrHPV self-sampling among a general population of non-participants [8]. One possible explanation for this difference is that WLWH may be less engaged with their GP, as their annual HIV check-ups also address broader health concerns, leading to infrequent GP visits and a more distanced patient-provider relationship. To improve follow-up rates, direct communication between the HIV clinic and the GP following a positive hrHPV test or offering a clinician-collected cervical sample at the HIV clinic may be beneficial.

Conclusions

This pilot study demonstrated that vaginal hrHPV self-sampling was an acceptable and feasible screening approach for WLWH, with high return rate among participants accepting to receive the self-sampling kit but suboptimal compliance to follow-up for the hrHPV positive cases. These findings highlight the need for strategies to enhance participation and follow-up adherence, ensuring that self-sampling initiatives effectively contribute to CC prevention in this population.

Going forward, larger multicenter studies are needed to validate these pilot findings and the value of more personalized screening approaches, including optimized self-sampling methods and targeted interventions to improve follow-up compliance.

Abbreviations

CC	Cervical Cancer
CIN	Cervical Intraepithelial Neoplasia
CPR	Civil Personal Registration Number
GP	General Practitioner
hrHPV	High Risk Human Papillomavirus
IQR	Interquartile range
VIA	Visual Inspection with Acetic Acid
WLWH	Women Living With HIV
WHO	World Health Organization

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Author contributions

All authors contributed significantly to the conception and design of the study. Data acquisition was done by SNHS, while analysis and interpretation of the data was carried out by SNHS and MT. SNHS was responsible for drafting the manuscript, MT, BA, LKP, MS and SJ revised it critically for important intellectual content and all authors provided final approval for the version to be published and accept responsibility for all aspects of the work.

Data availability

The datasets used and analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with ethical guidelines and principles for research involving human subjects. On November 9th, 2021, the Central Denmark Region Committee on Health Research Ethics reviewed and deemed this study as a quality improvement study (request approval j.no: 204/1-10-72-274-21). As such, the study was determined to be exempt from formal ethical approval under Danish regulations, as it falls within the scope of quality improvement rather than research requiring full ethical oversight. Clinical trial number: Not applicable. All participants were fully informed about the nature, purpose, and scope of the study. Verbal consent was obtained from all participants prior to their inclusion in the study. This approach was deemed appropriate given the minimal risk nature of the study and was conducted in accordance with the guidelines set forth by the Central Denmark Region Committee on Health Research Ethics. The confidentiality and privacy of participants were maintained throughout the study. All data collected were anonymized to prevent the identification of individual participants, and measures were taken to ensure that any information disclosed during the study was protected against unauthorized access. The findings from this study are intended to contribute to the continuous improvement of healthcare practices and patient outcomes within the Central Denmark Region.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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