ORIGINAL ARTICLE

Impact of Vaginal-Rectal Ultrasound Examinations with Covered and Low-Level Disinfected Transducers on Infectious Transmissions in France

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BACKGROUND. The risk of cross-infection from shared ultrasound probes in endorectal and vaginal ultrasonography due to low-level disinfection (LLD) is difficult to estimate because potential infections are also sexually transmitted diseases, and route of contamination is often difficult to establish. In France, the widely used standard for prevention of infections is through the use of probe covers and LLD of the ultrasound transducer by disinfectant wipes. We performed an in silico simulation based on a systematic review to estimate the number of patients infected after endorectal or vaginal ultrasonography examination using LLD for probes.

STUDY DESIGN. We performed a stochastic Monte Carlo computer simulation to produce hypothetical cohorts for a population of 4 million annual ultrasound examinations performed in France, and we estimated the number of infected patients for human immunodeficiency virus (HIV), herpes simplex virus, hepatitis B virus, hepatitis C virus, human papilloma virus, cytomegalovirus, and *Chlamydia trachomatis*. Modeling parameters were estimated by meta-analysis when possible.

RESULTS. The probability of infection from a contaminated probe ranged from 1% to 6%, depending on the pathogen. For cases of HIV infection, this would result in approximately 60 infected patients per year. For other common viral infections, the number of new cases ranged from 1,600 to 15,000 per year that could be attributable directly to ultrasound and LLD procedures.

CONCLUSIONS. Our simulation results showed that, despite cumulative use of probe cover and LLD, there were still some cases of de novo infection that may be attributable to ultrasound procedures. These cases are preventable by reviewing the currently used LLD and/or upgrading LLD to high-level disinfection, as recommended by the US Centers for Disease Control and Prevention.

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In ultrasonography, a vaginal probe and all endocavitary probes without a probe cover are considered semicritical devices, because they have direct contact with mucous membranes (eg, vagina, rectum, and pharynx). Endorectal and vaginal ultrasonography are widely used as important diagnostic tools in gynecology, obstetrics, and urology. Such endocavitary ultrasonography is seen as a harmless procedure because of the absence of ionizing radiation. However, the cost of transducers precludes a single-use-only strategy. Endovaginal and transrectal ultrasonography are considered as at least medium-risk procedures, in which "semicritical" instruments come into contact with mucous membranes and require high-level disinfection (HLD) rather than sterilization.[1-3] Although endocavitary ultrasonography probes might be considered even less critical instruments, because they are routinely protected by single-use disposable probe covers, leakage rates of 0.9%–2% for condoms and 8%–81% for commercial probe covers have been reported in the literature.[4]

For maximum safety, the key infection control issue concerns the risk of contamination and the need for specific cleaning and disinfection procedures to ensure a high degree of protection against infectious disease transmission even when a disposable cover is used, as recommended in the United States, Canada, and Australia.[1-3,5] Cleaning with a detergent and water solution is important as the first step in proper disinfection, because chemical disinfectants act more effectively on clean surfaces. Because of the potential disruption of the barrier sheath, additional HLD with chemical agents (eg, glutaraldehyde, aldehydes, and hydrogen peroxide) is necessary. Least desirable, but routinely used, are wipe

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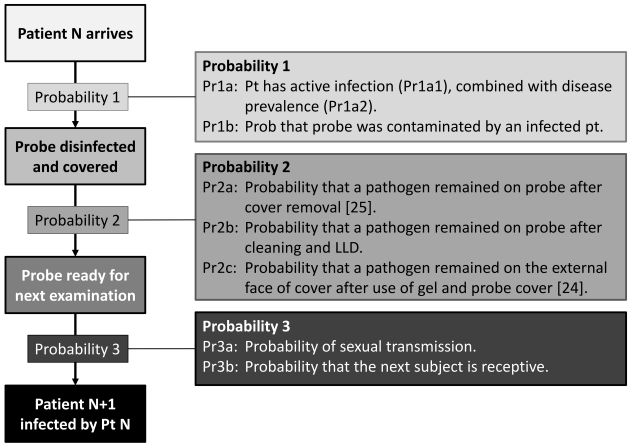

FIGURE 1. Model steps. LLD, low-level disinfection; Prob, probability; Pt, patient.

disinfection methods, often containing quaternary ammonium compounds, which are classified as a low-level disinfection (LLD) method.

The main pathogens of concern for both transrectal and endovaginal ultrasound examinations are human immunodeficiency virus (HIV), cytomegalovirus (CMV), human papilloma virus (HPV), enteric gram-negative pathogens (eg, *Escherichia coli* and *Klebsiella* species). *Clostridium difficile* is a pathogen of specific concern for transrectal ultrasound, and *Neisseria gonorrhoeae* and *Treponema pallidum* (syphilis) are specific concerns for endovaginal ultrasound. A recent systematic review and meta-analysis estimated a pooled prevalence of 12.9% (95% confidence interval [CI], 1.7%–24.3%) for pathogenic bacteria remaining on the probe after cleaning and LLD, even when a disposable cover is used, and 1.0% (95% CI, 0.0%–10.0%) for frequently occurring viruses (HPV, herpes simplex virus [HSV], and CMV) on endovaginal and rectal probes.[6] The pooled prevalence of infected patients after transrectal ultrasound and guided biopsies was estimated to be 3.1% (95% CI, 1.6%–4.3%). However, the systematic review confirmed that very few cases of contaminated patients with an established route of contamination from endocavitary ultrasonography had been reported. This finding does not mean that infectious risk of bacterial and viral transmission attributable to shared probes between patients and failure of LLD procedures does not exist. The key question is to estimate it in the presence of daily LLD practice, despite the use of a disposable cover.

An attempt to estimate the number of patients infected by endovaginal ultrasonography probes has been made by the French Sanitary Institute (INVS).[7] However, the modeling techniques used were relatively crude, applying a multiplicative model, assuming that an infected patient would only infect the following one and not taking into account how probe covers and their manipulation before cleaning the probe would affect the amount of virus or bacteria left on the probe head. Our objective was to perform a more sophisticated modeling combined with the previous meta-analysis to specify this infectious risk for broader infectious agents. Our models focused on viral and bacterial quantitative variation across the patient flow and were dependent on (i) the order of infected (or uninfected) patients and (ii) the microorganism's ability to stay on the probe after removal of the cover. After quantifying these parameters, our model could then be turned into an infection risk estimate for patients.

METHODS

Study Design

A flexible, detailed simulation model was built to estimate the number of patients annually who are exposed an infectious disease by means of a contaminated ultrasonography probe.

Mathematical Model Building

A stochastic Monte Carlo computer simulation produced hypothetical cohort data for a population of 4 million examinations performed annually in France.[8] Our model steps are shown in Figure 1, and the modeling was restricted to vaginal and/or rectal ultrasonography examination without any invasive procedures (eg, needle biopsies). Our simulations required the following probabilities to be specified into the model to compute the risk of having a vaginal-rectal ultrasonography-transmitted infection with an LLD and covered probe:

- Probability 1 was a combination of (i) the probability that a random patient underwent the examination with an active infection and presence of the pathogen in the vaginal or rectal mucosa and corresponding fluids (Pr1a) and (ii) the probability that the infected patient contaminated the covered probe or the handles of the probe during an examination (Pr1b).
- Probability 2 resulted from the standard operating procedure of preparing the probe for the next patient (sheath removal, Pr2a; LLD, Pr2b; new cover and gel, Pr2c). Probability 2 is the probability that the probe remained contaminated just before the next examination despite adherence to standard disinfection procedures.
- Probability 3 was the probability that the probe contaminated the new patient, as a combination of probability of pathogen transmission from the covered probe to the new patient (Pr3a), with the probability that the next patient was potentially receptive (Pr3b).

We built a model for each of the following pathogens that we considered to be most relevant in an ultrasonography setting: HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), HPV, HSV, CMV, and *Chlamydia trachomatis*. Of note, the pathogens that we considered persist on inert surfaces for longer than several hours, and we did not include the time

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TABLE 1. Parameters Used in Simulations

Pathogen	Probability 1		Probability 2		Probability 3	
	Pr1a2 (disease prevalence)	Pr1b (transmission from patient to probe)	Pr2b (probability that a pathogen remained after cleaning/LLD)	Pr2c (pathogen transmission to cover exterior despite gel and sheath; our data)	Pr3a (probability of probe contamination from an infected patient)	Pr3b (potentially receptive patients)[a]
HIV	0.0021[24]	0.2	0.756[13,15b]	0.023–0.147	0.0015[25]	1.00
HBV	0.0065[26c]	0.8	0.756[13,15b]	0.023–0.147	0.55[17,18d]	0.35[13]
HCV	0.0053[26e]	0.3	0.756[13,15b]	0.023–0.147	0.005[27,28]	1.00
HSV2	0.18[29,30]	0.5	0.756[13,15b]	0.023–0.147	0.036[20]	0.82[29,30]
HPV						
Baseline model	0.08[19f]	0.5	0.756[13,15b]	0.023–0.147	0.56[31,32]	0.92[19]
Empirical model	…	…	0.049[21b]	0.023–0.147	0.56[31,32]	0.92[19]
CMV	0.5[33,34]	0.5	0.756[13,15b]	0.023–0.147	0.04[20g]	0.50[18,20]
Chlamydia trachomatis	0.015[20]	0.5	0.756[13,15b]	0.023–0.147	0.5[35-37]	0.985[20]

NOTE. Our estimate for Pr2a across all pathogens was 8.9%, from the Kac et al[13] study. CMV, cytomegalovirus; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HPV, human papilloma virus; HSV2, herpes simplex virus type 2; LLD, low-level disinfection.

[a] Evaluated as (1 − disease prevalence) or (1 − prevalence of vaccinated people).

[b] Results from pooling data using a meta-analysis technique; see "Methods."

[c] Prevalence of hepatitis B surface antigen–positive individuals.

[d] This was estimated on the basis of the median of the range of probabilities of sexual transmission.[26,30]

[e] Prevalence of individuals with an active HCV infection (ie, HCV RNA positive).[30]

[f] The probability of sexual transmission ranged from 5% to 100% according to Burchell et al,[19] with a median of 40% that was considered for estimating the probability of probe transmission from an infected patient.

[g] The sexual transmission probability remained unknown; we approximated with the only available data in the literature, which was for CMV transmission related to breast-feeding.[20]

period between 2 examinations in our model. The assumed values for each pathogen's parameters used as probability estimates in the simulations are summarized in Table 1.

The Pr1a estimate was based on the pathogen prevalence and its presence in human fluids, such as vaginal secretion. For each random patient who entered into the ultrasonography clinic, the Pr1a estimate was the probability in a Bernoulli trial (0 = no infection, 1 = infection) to determine whether the patient carried an active infection. Consequently, we simulated a group of patients with active infections from a binomial distribution with probability Pr1a. In the case of HBV and HCV, we estimated the probability of Pr1a2 from the population-based prevalence of patients who were hepatitis B surface antigen positive and the population-based prevalence of patients with an active HCV infection (ie, HCV RNA positive), respectively.[9]

Pr1b estimated the pathogen transmission from an infected patient to the external surface of the probe cover. Very few data were available in the literature: only patients with AIDS were found to be able to contaminate semicritical dental devices;[10] risk of contamination for dental devices was found to be 0%–60% for HCV[11] and 15%–75% for HBV.[12] We estimated Pr1b using the percentage proposed by a consensus of experts.[9] The covered probe was considered to be exposed to the pathogen from a Bernoulli trial with probability Pr1b.

Probability Pr2a that a pathogen is found on the probe after sheath removal was obtained from the Kac et al[13] study. In this study, the viral genomes of HPC, CMV, and EBV were searched on the endovaginal or endorectal probe covers after examination just before removing the cover and then on the probes after sheath removal.[13] The authors estimated that 8.9% (95% CI, 3.5%–19.7%) of the probes are contaminated with the pathogen when the pathogen was found on the probe cover. Probability Pr2b that a pathogen remained on the probe after cleaning and LLD was obtained by pooling data from 2 studies using a meta-analysis calculation approach.[14,15] For Pr2b estimation, we assumed that LLD was as effective for viruses as for bacteria, although this assumption is arguable.

Our group empirically estimated the probability (Pr2c) that the contamination remaining on the probe would contaminate the next patient despite use of new gel and new cover. We estimated this probability by an experiment in a controlled radiologic clinic setting. These results are described in detail in M'Zali et al,[16] but we summarize the experiment here. This experiment was to simulate a routine examination. The materials included a blue phantom mannequin used for vaginal ultrasound medical training, Conformité Européenne probe covers (recommended in France), and an ultrasound system. We used a strain of *Pseudomonas aeruginosa* as the source of contamination into which the probe was soaked. We measured the number of times that the exterior surface of the

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TABLE 2. Results of Simulations across All Pathogens

Pathogen	No. of patients, mean ± SD		
	Patients arriving with active infection	Probe becomes contaminated for next ultrasonography patient despite LLD and use of probe covers	Uninfected patients leaving with infection after ultrasonography examination
HIV	8,392 ± 197	1,274 ± 75	40 ± 20
HBV	26,033 ± 319	15,738 ± 248	1,383 ± 164
HCV	21,177 ± 315	4,789 ± 151	151 ± 63
HSV2	719,914 ± 1,459	86,574 ± 583	9,707 ± 2,900
HPV			
Baseline model	319,961 ± 1,025	15,709 ± 274	8,085 ± 193
Empirical model	…	…	14,848 ± 255
CMV	2.0E+06 ± 1,895	755,959 ± 1,532	22,549 ± 7,690
Chlamydia trachomatis	60,017 ± 511	22,680 ± 277	4,025 ± 183

NOTE. CMV, cytomegalovirus; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HPV, human papilloma virus; HSV2, herpes simplex virus type 2; LLD, low-level disinfection; SD, standard deviation.

probe cover and the mannequin were contaminated with *P. aeruginosa* under routine examination conditions, and these estimates were our basis for Pr2c.

Pr3a estimates were assumed to be similar to the probability of sexual transmission of the pathogen, when available (eg, the Pr3a estimate for HBV).[17,18] If these estimates were not available, it was assumed to be equivalent to accidental blood exposure risk. The probability of sexual transmission of HPV ranged from 5% to 100% according to Burchell et al,[19] with a median of 40% that was considered for estimating the probability of probe transmission from an infected patient. Data for the sexual transmission probability of CMV was not available; we approximated the sexual transmission probability of CMV by the probability of transmission from breast-feeding.[20] Pr3b represented the potentially receptive patients percentage (eg, 100%) for HIV or HCV but took into account prevalence of disease when the disease was more frequent (CMV, HPS, and HSV2) or the prevalence of vaccinated people (HBV).

Casalegno et al[21] estimated in a cohort study the number of ultrasonography probes contaminated by HPV just before the next patient in a cohort study of patients who underwent endovaginal ultrasonography examination. Based on this study, and for HPV specifically, we constructed 2 models: an "empirical model" and the baseline (BL) HPV model. The BL HPV model is comparable to the simulation model that we considered for the other pathogens. In the "empirical model," HPV probabilities of Pr1b to Pr2b, inclusive, were estimated empirically by pooling results from Casalegno et al[21] and our data using a meta-analysis calculation approach described elsewhere.

The mathematical modeling is further described in the Appendix. The following are the key assumptions for our model:

- Every step in the probe contamination/decontamination process was considered as an independent trial, with the exception that we allowed for the possibility of a contaminated probe infecting every subsequent subject until the probe was decontaminated or 20 examinations.
- Patients were drawn from a random Bernoulli trial with the probability of infection equal to the prevalence of pathogen.
- Transmission probabilities were the ones previously defined and appear in Table 1.
- Modeling did not take into account that patients may have contracted more than 1 infection; we assumed that transmission of more than 1 pathogen resulting in multiple infections per patient or per probe is unlikely.
- We did not account for differences between vaginal or rectal mucosa, either in probability of transmission or probability of infection.

After discussion with experts in the field, we used a geometric distribution with a probability that the pathogen remained on the probe to simulate who was at risk for contamination when examined after an infected patient. However, the geometric distribution was truncated at a limit of at most 20 patients subsequent to the index case patient. The simulation programming was performed in the R statistical computing language.[22]

RESULTS

Estimated Parameters Used for the Modeling

All parameters used for the modeling are presented in Table 1. Pr1a2, Pr1b, Pr2c, Pr3a, and Pr3b came from literature with reference indexed. Pr2b was estimated at 0.756 after pooling data from relevant studies with a meta-analysis technique, and Pr1 to Pr2b inclusive was estimated at 0.049 for

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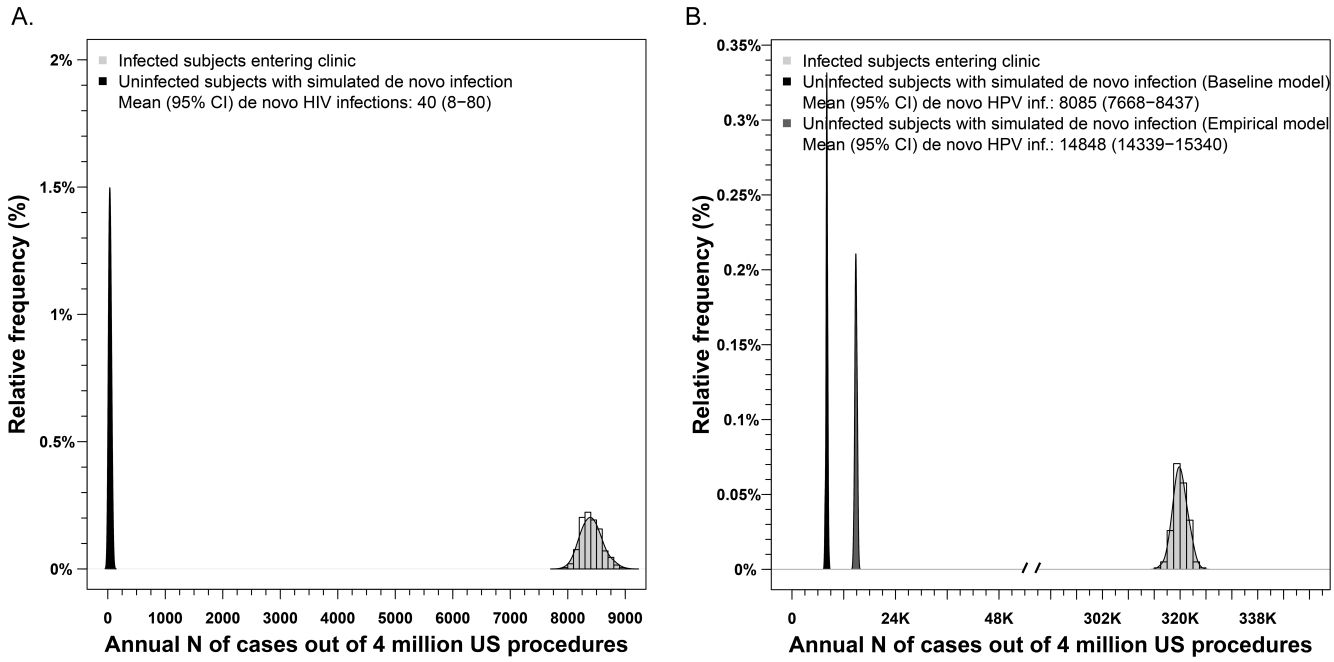

FIGURE 2. Example Monte Carlo simulation results from the assumptions in Table 1. Histograms and kernel density estimates are of human immunodeficiency virus (HIV; *A*) and human papilloma virus (HPV; *B*). The 2 competing models for HPV are shown in black (baseline model) and dark gray (model based on empirical data). CI, confidence interval; inf, infections.

the HPV empirical model. For all pathogens, Pr2a was 8.9% (95% CI, 3.5%–19.7%) based on the study by Kac et al.[13]

Modeling Results

The results of 4 million simulations per pathogen appear in Table 2. First, the number of infected patients who arrived for ultrasonography matched reasonably with the assumed disease prevalence in the Pr1a2 column of Table 1. The simulated rates of an infected patient contaminating a probe despite LLD procedures ranged from 5% in the case of HPV to over 30% for CMV and *C. trachomatis*. The rate of infection transmission from an infected patient to an uninfected patient ranged from 0.7% for HIV (63 of 8,392) to over 6% for both HCV and *C. trachomatis*.

We had 2 methods of estimating the number of new HPV infections due to ultrasonography. The first method, the BL model, used the same simulation that we applied to the other pathogens. However, Casalegno et al[21] and our empirical data addressed the same question in HPV with empirical data. This reduced our simulation complexity; in the empirical HPV model, we only applied the probabilities to the transmission of HPV to an uninfected patient from the step when HPV is transferred from the contaminated probe to the exterior of the probe cover. The results of the HPV BL and empirical HPV models had similar estimates of de novo infection cases. The BL model, despite its complexity, gave more conservative estimates of cases than the more empirically based HPV model. This may be an indication that our simulated number of cases may be similarly conservative for the other pathogens.

Figure 2 shows 2 examples of the simulation results for 2 of the pathogen results in Table 2. The plot in Figure 2*A* shows the estimated number of patients with cases of HIV infection who arrive for an ultrasonography examination per year in France and our estimate for the resulting simulated number of uninfected patients who are exposed to and are infected by a probe contaminated by HIV. The plot in Figure 2*B* has a similar interpretation for the 2 HPV models. Our simulated HPV results were consistent and suggest that the estimates mirror the actual number of HPV infections resulting from ultrasonography due to our use of the published empirical data for probe contamination.

DISCUSSION

It is understood that there are risks of endocavity infection for any diagnostic procedure in which the instrument is not intended for single-patient use. There are differing opinions as to how to quantify the risk in the endorectal and vaginal ultrasonography setting. Although all practitioners understand that the risk of a contaminated ultrasonography probe is nonzero, there has not been an attempt thus far to synthesize and summarize the existing data across a broad spectrum of pathogens.

Building on our recent results,[6,23] we considered a systematic review of the available published data from ultrasonog-

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raphy clinics in France to estimate the probabilities at each step in the process of pathogen transmission during ultrasonography. Our approach extends an earlier in silico study by the French Sanitary Institute.[7] The rates of de novo infected cases from our simulations range between 1% and 6% risk for the procedures that we considered. These cases are likely to go undetected by health authorities, and patients often do not self-report infections that were attributable to ultrasonography. This may explain why there are no available data published in the literature. Our simulation study is, to our knowledge, the first one in this area of research and provides the first estimation of the infectious risk related to endovaginal and endorectal ultrasonography covered probes after LLD procedures.

There are limitations to our findings. Our risk estimates are population based and not age corrected. The probability assumptions on which our simulations were built tended to be point estimates from relatively small studies. Some probability estimates, such as the probability of pathogen transmission to external cover after application of gel and a sheath, were used across multiple pathogens. However, it may be the case that this estimate is suitable only for a specific pathogen; we were unable to find comparable probabilities for each pathogen of interest. Other limitations include the probabilistic assumptions of our model. We assumed independence of the efficacy of disinfection methods and probe covers. It is more likely that infection control standards vary widely between ultrasonography clinics. It is not possible to model these types of clinic-to-clinic variations without supportive data, but these data are difficult and expensive to collect from both a sampling and a laboratory perspective. Finally, we possibly overestimated the number of HIV-infected patients after ultrasonography examination, because Pr2b used for modeling estimated LLD efficacy for bacteria. However, HIV is a fragile virus for which LLD efficacy may be higher than it is for bacteria.

Despite these limitations, our simulation results may draw attention to the cost in terms of patients and illness due to current infection control standards across ultrasonography clinics in France. We believe that it is possible to reduce significantly the number of new cases of infection estimated in our study arising from contaminated ultrasound probes with enhanced disinfection procedures and standards. Our estimates indicated that 5%–30% of infections can be eliminated by introducing improved standards for those clinics that rely on LLD. Indeed, in contrast to LLD, HLD has been shown to be up to 100% effective in different settings. Kac et al[13] reported that 3.4% of endovaginal and transrectal transducers were contaminated by pathogenic bacteria and that 1.5% had viral contamination, all of which contamination disappeared after ultraviolet-C HLD.[23] When our estimated number of cases is multiplied by the lifetime cost to treat patients with these types of infections, increased infection control procedures may be worth the investment.

In conclusion, our data synthesis of the infectious disease literature and corresponding simulations showed that there may be a case to be made for improved infection control procedures in ultrasonography clinics where endocavitary ultrasonography probes are used routinely. There is a need for this topic to receive additional study, particularly in areas that do not put ultrasonography patients at risk. Simulation studies and studies with blue phantom mannequins may still serve to improve upon the state of the data until additional data on humans are available.

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APPENDIX

This is an example of our simulation of patient flow. First, we simulate a series of patients. In this example, we will assume 10 patients who arrive in an ultrasonography clinic in France (Table A1).

Which of the Patients Has an Active Infection?

Each of the 10 women has a probability of walking into the clinic with an active viral infection (probability Pr1a). For this example, we will use an arbitrary probability of Pr1a = 10% of a viral pathogen in the general population.

Patient 5 and Patient 7 have an infection. This puts the subsequent patients at risk for infection.

Next, we will simulate whether the probe is contaminated by the pathogen. This probability is Pr1b. For this example

TABLE A1. Simulated Patients

Patient	Active infection?	Simulation result
1	No	Patient does not carry an active pathogen
2	No	No active pathogen
3	No	No active pathogen
4	No	No active pathogen
5	Yes	Patient is carrying an active pathogen
6	No	No active pathogen
7	Yes	Patient is carrying an active pathogen
8	No	No active pathogen
9	No	No active pathogen
10	No	No active pathogen

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with 10 patients, we will assume that the Pr1b probability is a constant probability of 0.20.

Did Probe Become Contaminated?

First, we will simulate whether patient 5 infects the probe. For our simulation's Bernoulli trial, we perform a biased coin toss with the probability of infection. For example, if the random number generator gives 0.2 or less, then patient 5 has contaminated the probe. If the random number generator is greater than 0.2, then there is no infection.

Who May Be at Risk from Contamination?

Patient 6 and patients 8–10 may be at risk of an infected probe. However, our simulation assumes that patient 7 is not at risk from patient 5, because patient 7 already has the infection in question. Additionally, the risk of infection is not cumulative for patients 8 through 10; we assume that they may only be infected by the most recent patient with an active infection (patient 7 in this example).

In the case in which an infected patient has an ultrasound and contaminates the probe, the simulation chooses how many subsequent patients are at risk. The number of subsequent patients who may be infected was drawn from a truncated geometric distribution.

Did Probe Become Contaminated Despite LLD?

The simulation checks whether the probe is cleaned with probability Pr2a, once per patient, for each patient.

Did the Probe Cover Prevent Infection?

Similarly, we can simulate whether the infection is transferred to the exterior of the probe cover. This is probability Pr2b.

If the probe has been disinfected or if the infection was not transferred to the exterior of the probe cover, then there is no risk of contamination to the next patient. If both the LLD and the probe cover failed to prevent the infection, then the probe has become contaminated for the next uninfected patient. The probability of transmission from probe to patient is Pr3a. For most of our pathogens, we assumed that the probability of the infection being transmitted from the probe to the next uninfected patient was approximately the same as a sexual transmission.

Finally, the subject may not be receptive to the infection. That probability is modeled by Pr3b.

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