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SUPPLEMENT ARTICLE

Cost-effectiveness of Ward Closure to Control Outbreaks of Norovirus Infection in United Kingdom National Health Service Hospitals

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Background. Norovirus is the most common cause of outbreaks of acute gastroenteritis in National Health Service hospitals in the United Kingdom. Wards (units) are often closed to new admissions to stop the spread of the virus, but there is limited evidence describing the cost-effectiveness of ward closure.

Methods. An economic analysis based on the results from a large, prospective, active-surveillance study of gastroenteritis outbreaks in hospitals and from an epidemic simulation study compared alternative ward closure options evaluated at different time points since first infection, assuming different efficacies of ward closure.

Results. A total of 232 gastroenteritis outbreaks occurring in 14 hospitals over a 1-year period were analyzed. The risk of a new outbreak in a hospital is significantly associated with the number of admission, general medical, and long-stay wards that are concurrently affected but is less affected by the level of community transmission. Ward closure leads to higher costs but reduces the number of new outbreaks by 6%–56% and the number of clinical cases by 1%–55%, depending on the efficacy of the intervention. The incremental cost per outbreak averted varies from £10 000 ($14 000) to £306 000 ($428 000), and the cost per case averted varies from £500 ($700) to £61 000 ($85 000). The cost-effectiveness of ward closure decreases as the efficacy of the intervention increases, and the cost-effectiveness increases with the timing of the intervention. The efficacy of ward closure is critical from a cost-effectiveness perspective.

Conclusions. Ward closure may be cost-effective, particularly if targeted to high-throughput units.

Keywords. norovirus; outbreak; ward closure; cost-effectiveness.

Noroviruses are the most common cause of gastroenteritis outbreaks in United Kingdom National Health Service (NHS) hospitals [1]. These outbreaks lead to patient morbidity resulting in extended length of stay and occasionally mortality. They also cause additional costs associated with treatment provision and bed-days lost due to temporary closure of wards, as well as productivity losses associated with infected hospital staff. One estimate suggested that gastroenteritis outbreaks cost the NHS about £115 million in 2002–2003 [2]. Surveillance of gastroenteritis outbreak data from 1992 to 2000 captured data on >5000 outbreaks during this period; >50% of these outbreaks were caused by norovirus [2, 3]; nearly 1000 hospital outbreaks are now reported annually in England [4]. It is difficult to control such outbreaks because there is a large reservoir of virus in the community and efficient transmission from person to person via exposure to contaminated fomites or inhalation of infectious particles from vomitus aerosols [5]. Moreover, there is a significant amount of patient and staff movement within and between hospital wards, which may contribute to the spread of norovirus from affected to nonaffected areas. Nosocomial outbreaks of norovirus can lead to ward closures and even hospital closures, with a major impact on the functional ability of a hospital and its resources [6]. Infection control measures are targeted to minimize the transmission of norovirus both between and within wards. Control measures include cohort nursing of affected patients, exclusion of affected staff until 48 hours after recovery, and rigorous disinfection of affected wards. However, recent guidelines for the United Kingdom have shifted away from closing wards to new patient admissions [7] because it is highly disruptive and costly.

However, there is limited evidence for the effectiveness of ward closure to control and contain outbreaks [1] and, if effective, whether it is a cost-effective strategy. Using a detailed prospective data set on norovirus infection outbreaks from 14 hospitals in southwest England, we estimated the cost-effectiveness of ward closure, taking into account the risk of infection from the community, the risk of infection from within the hospital, and the timing of the intervention.

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METHODS

Data

We used data from an intensive active-surveillance program for outbreaks of gastroenteritis in Avon, England, collected over 1 year (from April 2002 through March 2003). Details of the study population and outbreak investigation are provided elsewhere [1]. An outbreak was defined as ≥2 cases occurring in a functional care unit (usually a hospital ward) with dates of onset within 7 days of each other. A patient or healthcare worker (HCW) satisfying one of the following conditions was defined as a case: (1) ≥2 episodes of vomiting in a 24 hour period or ≥2 loose stools in a 24-hour period or (2) ≥1 episode of both vomiting and loose stool in a 24-hour period. The first and last dates of an outbreak were determined from the date of onset in these respective cases. Data were available from 171 inpatient wards from the 14 hospitals (4 large, acute care hospitals and 10 community hospitals) in the region; wards were categorized as either admission, general medical, or long-stay wards. In addition, if a ward was closed to new admissions, the dates of closure were reported.

Transmission Analysis

To investigate the transmission of norovirus from the community and within the hospital, we constructed a data set of daily counts of outbreaks for each hospital from the active-surveillance data. The data were stratified by ward type (admission, general medical, and long-stay) and ward status (whether the ward was open or closed to new admissions on a given day). To estimate the importance of introduction of virus from the community, we extracted weekly data on the number of norovirus laboratory reports for all of England and Wales from the national surveillance database [8]. Underascertainment of community cases is substantial through this system [9], but we assumed that the seasonal pattern of laboratory reports generally reflects the incidence in the community.

The primary outcome variable of the transmission analysis was the daily number of new outbreaks in all wards in a hospital. To quantify the extent to which outbreaks in different ward types (admission, general medical, and long-stay) were a risk factor for further outbreaks in the same hospital, we used a random-effects negative binomial regression model. The model included a random-effects term (treating "hospital" as a random variable) to allow for the clustering of outbreaks within hospitals that may result from local transmission. The analysis was performed in R [10]. In the regression analysis, we also estimated the effect of community transmission and controlled for type of hospital (acute care or community). We used an identity link function in the regression because the expected number of new outbreaks in the hospital is likely to be an additive function of outbreaks in all different wards. We accounted for the fact that wards currently experiencing outbreaks would not be at risk of (ie, not susceptible to) an incident outbreak. The risk exposure of each type of ward was adjusted by the number of susceptible (unaffected) wards in that day in the corresponding hospital as a whole. A summary of key variables is given in Supplementary Table 1.

Epidemic Simulation Model

We developed an epidemic simulation model to determine how an outbreak can spread between wards of an acute care NHS hospital and the implications of ward closure policy to control a norovirus infection outbreak. In the epidemic model, we simulated the effect of ward closure, using a range of scenarios, and then assessed the cost-effectiveness of ward closure for these different scenarios.

Ward closure was characterized by the timing and efficacy of the intervention. Time points considered a priori were 1, 3, and 5 days since detection of the first infection. To quantify the effect of ward closure on the frequency of subsequent outbreaks and of clinical cases in HCWs and patients, we used the parameter estimates from the regression model to inform a stochastic discrete-time ward-level norovirus transmission model. This simulation model captured between-ward transmissions of norovirus. We assumed that closing wards will reduce between-ward infectiousness (defined as the probability that an outbreak ward causes infection on an outbreak-free ward) by 0%, 25%, or 50%. The effectiveness of ward closure depends on a number of factors, including the intervention's inherent ability to reduce transmission, the intervention's intensity and time of initiation, and compliance with the intervention. However, the effectiveness of ward closure during norovirus infection outbreaks has not been clearly established, and evidence is lacking in this regard. There is some weak evidence that ward closure is effective at limiting case numbers [11, 12], but there are no data on between-ward spread of infection. We have therefore considered a plausible range for the values of the effectiveness of ward closure at preventing between-ward spread of infection. This model simulated the number of admission (*adm*), general medical (*gm*), and long-stay (*ls*) wards that, at time *t*, were (1) uninfected and susceptible (*S*) to infection, defined as $S_{adm}(t)$, $S_{gm}(t)$, and $S_{ls}(t)$; (2) experiencing ongoing norovirus outbreaks but still open (*O*) to new admissions, defined as $O_{adm}(t)$, $O_{gm}(t)$, and $O_{ls}(t)$; and (3) experiencing ongoing outbreaks but closed (*C*) to new admissions, defined as $C_{adm}(t)$, $C_{gm}(t)$, and $C_{ls}(t)$. This required specifying the number of new wards to infect at each time step and the number of wards of each type where outbreaks ended at each time step.

A time step of 1 day was used, and each day the number of new wards infected was drawn from a negative binomial distribution, with the mean calculated as

$$a_0 L(t) + a_1 O_{\mathrm{adm}}(t) + a_2 O_{\mathrm{gm}}(t) + a_3 O_{\mathrm{ls}}(t) + (1-f) a_1 C_{\mathrm{adm}}(t) + (1-f) a_2 C_{\mathrm{gm}}(t) + (1-f) a_3 C_{\mathrm{ls}}(t),$$

where $L(t)$ is the number of laboratory reports for that day (representing community transmission), the coefficients a_i are taken

from the regression analysis, and f is the efficacy of ward closure at preventing infection on other wards (assumed to be 0%, 25%, or 50%). If the selected number of new wards infected exceeded $S_{adm}(t) + S_{gm}(t) + S_{ls}(t)$, all susceptible wards were infected. The negative binomial dispersion parameter was also estimated from the regression model described above.

The daily probabilities of an outbreak ending were estimated from the surveillance data at the hospital level. We assumed that these probabilities were similar across types of wards but differed according to ward status. The probabilities were estimated in 2 steps. First, the survival probability of a ward remaining affected on each day since first infection was calculated from the surveillance data. Second, the probability of an ongoing ward outbreak coming to an end each day was calculated as the difference of recovery probability between day t and $t - 1$ since detection of the first infection. We assumed that all wards recover completely within 3 weeks, as outbreaks rarely persist after this period in a single ward. The cumulative probabilities of recovery are lower in open wards, compared with closed wards (Supplementary Figure 1).

The simulation model was run for 365 days and 100 000 times for each scenario. We report the mean number of new outbreaks, the number of outbreak-days when the ward was closed, and number of outbreak-days when the ward was open. This epidemiological model was implemented in R. The simulation code is available in the Supplementary Technical Appendix.

Economic Analysis

The economic analysis was based on the results of the epidemiological model. We measured the costs and benefits of hospital closure at different time points since the first infection, assuming different efficacies for the effect on between-ward transmission. The primary and secondary outcome measures were cost per case and cost per outbreak avoided, respectively. The perspective is that of a typical acute care hospital. Bed-days lost associated with closure of wards (units) to new admissions and lost productivity of healthcare staff due to sickness were considered as the 2 main sources of costs related to an outbreak of norovirus infection. Since NHS hospitals operate at >95% occupancy of inpatient beds, a lost bed-day is a real economic loss in terms of opportunity costs. Similarly, staff absence due to illness is another key opportunity costs in terms of paid productivity loss related to an outbreak. There are other sources of cost due to cancelled operations, overuse of beds caused by delayed discharge, additional cleaning services, and increased drug prescribing. However, these costs are likely to be relatively small [1], and they have not been empirically quantified. The cost of bed-days differs substantially by unit specialty, so the costs are reported for each type of ward separately and for the hospital as a whole.

The amount of bed-days lost was estimated by multiplying the total days of closure by the mean bed-days lost for a day of closure. This loss was then transformed into monetary values by using the average unit cost of a hospital bed per day by ward type. The unit cost of a bed-day was taken from published sources [1, 13] and adjusted to 2011 price levels [14]. Staff absence was translated into monetary values by using the information on average length of staff absence (which includes the illness period and the 48-hour period of postrecovery isolation from work) multiplied by the unit cost of staff absence, based on cost of a practice nurse [14]. All parameter values of economic analysis are reported in Supplementary Table 2.

We report the incremental cost per outbreak avoided and the incremental cost per clinical case avoided for each ward closure option compared to no ward closure. We performed 1-way sensitivity analysis to examine the sensitivity of cost-effectiveness results to parameter values. In the 1-way sensitivity analyses, each parameter was changed over its range while all the other parameters remained fixed at their base-case level. One-way sensitivity analysis was only performed in the scenario in which the ward was closed after 3 days of onset and ward closure reduced between-ward infectivity by 25% for all ward types. A probabilistic sensitivity analysis was undertaken using a nested 2-level Monte Carlo method to evaluate the joint uncertainty of all parameter values. Economic parameters of interest were sampled 5000 times from their recommended distribution in the outer loop. Parameters for the transmission analysis were sampled 100 times in the inner loop, where each sample represented the average of 500 randomly selected data points. This nested approach was adopted to minimize the variability arising from the stochastic epidemic model because we were interested in the average behavior of the epidemic model. Results were then plotted on a cost-effectiveness plane. Cost-effectiveness acceptability curves (CEACs) [15] were constructed to report the probability that ward closure options were cost-effective for a range of willingness-to-pay thresholds for clinical cases avoided. CEACs were generated for all scenarios.

RESULTS

There were 232 new gastroenteritis outbreaks leading to 2494 outbreak-days in the study hospitals during the 1-year follow up period [1]. On average, there were 1.57, 1.41, and 1.12 new

Table 1. Number of New Outbreaks, Number of Wards, Rate of Outbreaks, and Outbreak Days During the Year of Active Surveillance

Variable	Admission Units	General Medical Units	Long-Stay Units
New outbreaks, total no.	11	183	38
Wards, no.	7	130	34
Outbreaks per ward, no.	1.57	1.41	1.12
Outbreak-days, total no.	134	1937	423

Data are from [1].

Table 2. Results of Transmission Risk Factor Analysis: Community-Level and Hospital-Level Norovirus Activity and Hospital Type Association With Onset of New Outbreaks

Parameter	Coefficient (95% CI)	*P* Values
Current outbreak(s) in admission ward[a]	0.229 (.080–.378)	.003
Current outbreak(s) in general medical wards[a]	0.067 (.048–.085)	<.001
Current outbreak(s) in long-stay wards[a]	0.050 (.005–.095)	.030
Community level of activity[b]	1.5E – 05 (1.1E – 5 to 1.9E – 05)	<.001
Type of hospital (acute tertiary care hospital vs smaller community hospital)	–0.008 (–.010 to –.006)	<.001
Hospital level variance	0.000	
No.	5087	

Abbreviation: CI, confidence interval.

[a]Per outbreak per day. These coefficients are a_1, a_2, and a_3 in the equation in the main text.

[b]Per norovirus laboratory report. This estimated coefficient is a_0 in the main text.

outbreaks for each admission, general medical, and long-stay ward per year (Table 1).

Transmission Analysis

The effects of explanatory variables (ongoing outbreaks in other hospital wards and community levels of norovirus activity) on the counts of new outbreak are reported in Table 2.

The estimated coefficients can be interpreted as the effect of the explanatory variable on new outbreaks per day in the hospital. An ongoing outbreak in an admission ward and a general medical ward increases the risk of a new outbreak by 22.9% and 6.7%, respectively. Thus, the additional daily risk of a new outbreak due to an ongoing outbreak in an admission ward is roughly 3 times that due to an ongoing outbreak in a general medical ward. The effect of an ongoing outbreak in a long-stay ward on the additional daily risk of new outbreaks is roughly similar (although perhaps somewhat smaller) to that of an ongoing outbreak in a general medical ward. There is a higher risk of a new outbreak associated with ongoing outbreak in an admission ward, compared with the risk associated with another type of ward (general medical or long stay), because an admission ward acts as a gateway between the community and different wards of the hospital. The community level of norovirus infection has a very small but statistically significant effect on the occurrence of new outbreaks. When the risk of a community-based outbreak is maximal (approximately 120 weekly national laboratory reports), the additional risk of norovirus infection outbreak on a ward is 0.2%. The results indicate that the additional risk of an outbreak associated with the community prevalence of norovirus infection is low, compared with that associated with ongoing hospital outbreaks. These results should be interpreted carefully because of the possibility of underascertainment of community cases when such cases are estimated on the basis of norovirus-associated laboratory results. The type of hospital (acute care or community) has a small but statistically significant effect on the frequency of new outbreaks, with tertiary care hospitals experiencing slightly lower risks. The parameter estimates from this analysis were

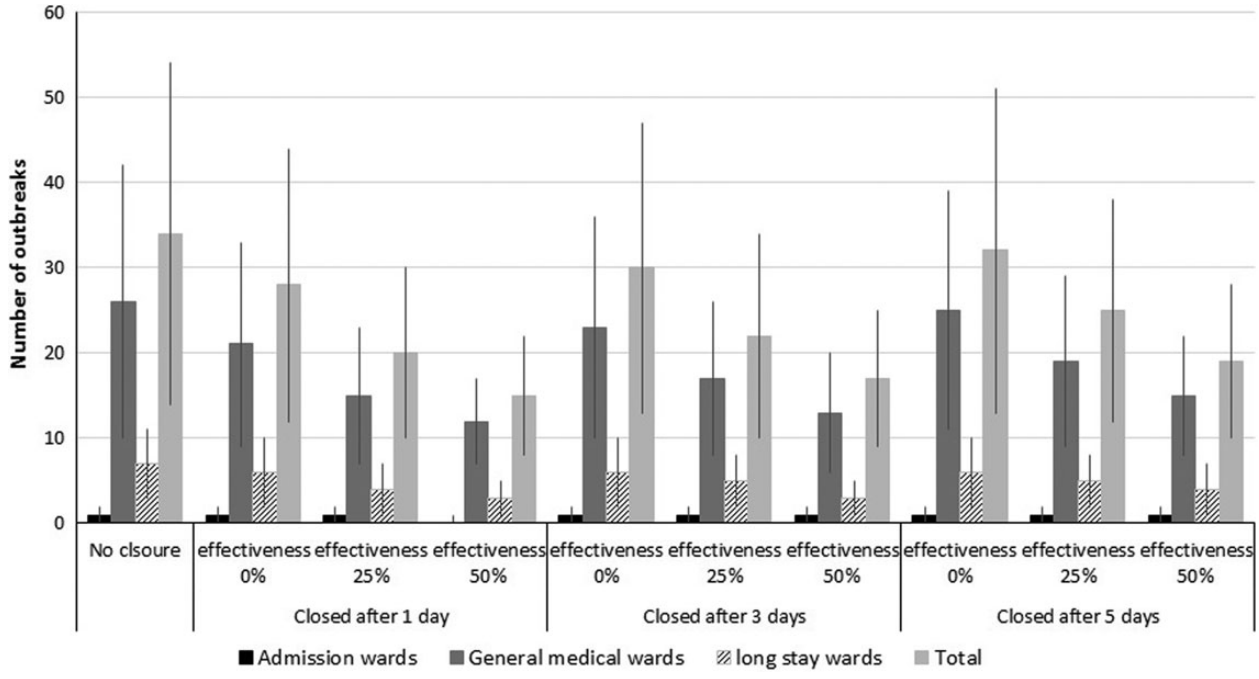

Figure 1. Mean number of outbreaks (±SD) per year, by type of ward, as estimated from the epidemic model.

Table 3. Mean Total Cost and Mean Effectiveness of Ward Closure Over 1 Year

Variable	No Closure	Closure 1 d After Onset, by Percentage Effectiveness			Closure 3 d After Onset, by Percentage Effectiveness			Closure 5 d After Onset, by Percentage Effectiveness		
		0	25	50	0	25	50	0	25	50
Cost, £, by cause										
Productivity loss	386 113	274 870	204 170	159 366	318 313	242 805	190 306	351 213	275 652	219 567
Bed-day loss	. . .	710 652	534 176	417 879	695 597	532 321	417 834	647 745	510 872	405 606
Total	386 113	985 521	738 346	577 244	1 013 910	775 126	608 140	998 959	786 524	625 173
Effects										
Days closed per year, total no.	. . .	266	198	154	260	198	155	242	191	152
Outbreaks per year, total no.	34	28	20	15	30	22	17	32	25	19
Duration of outbreak, d, mean	14	11	12	12	12	13	13	13	13	13
Clinical cases per year, total no.	705	544	404	315	630	481	377	695	546	435
Incremental cost-effectiveness, £										
Cost per outbreak avoided	. . .	95 312	24 923	9994	168 091	33 267	13 147	305 695	43 287	16 394
Cost per case avoided	. . .	3718	1170	490	8344	1731	676	60 571	2508	883

used in the simulation model, on which the economic analysis was based.

Epidemic Simulation

Ward closure is expected to reduce the number of new outbreaks (Figure 1), even when ward closure is assumed to have no direct impact on between-ward transmission. This is because ward closure also reduces the duration of an outbreak (and thus the duration of infectiousness to other wards). In a scenario with no control measures implemented, there will, on average, be 34 outbreaks in 29 wards in a typical acute care hospital over 1 year (Figure 1). Closing wards was predicted to reduce the expected annual number of outbreaks to between 15 (for ward closure 1 day after onset and 50% efficacy) and 32 (for closure 5 days after onset and 0% efficacy).

Economic Analysis

Uncontrolled norovirus infection outbreaks are estimated to cost a typical acute care hospital around £0.39 ($0.55) million per year (Table 3). The currency conversion factor that was used was £1 equals $1.4 (http://www.oecd.org/std/prices-ppp/purchasingpowerparitiespppsdata.htm). Intervening by closing

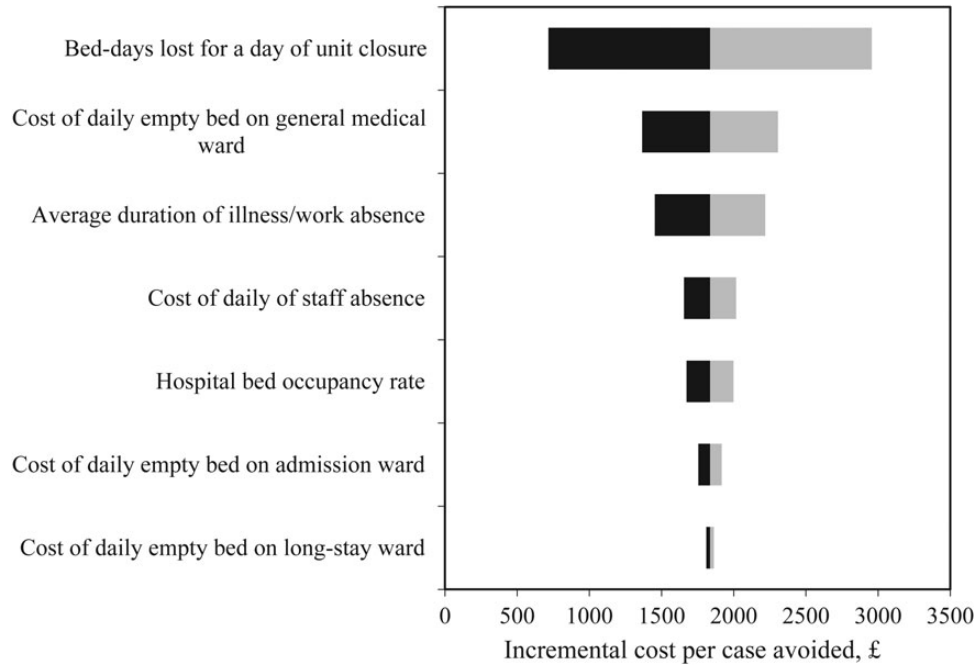

Figure 2. One-way sensitivity analysis showing the effect of varying each economic parameter on the incremental cost per case avoided for a scenario in which the ward was closed after 3 days and the efficacy of the intervention was 25%.

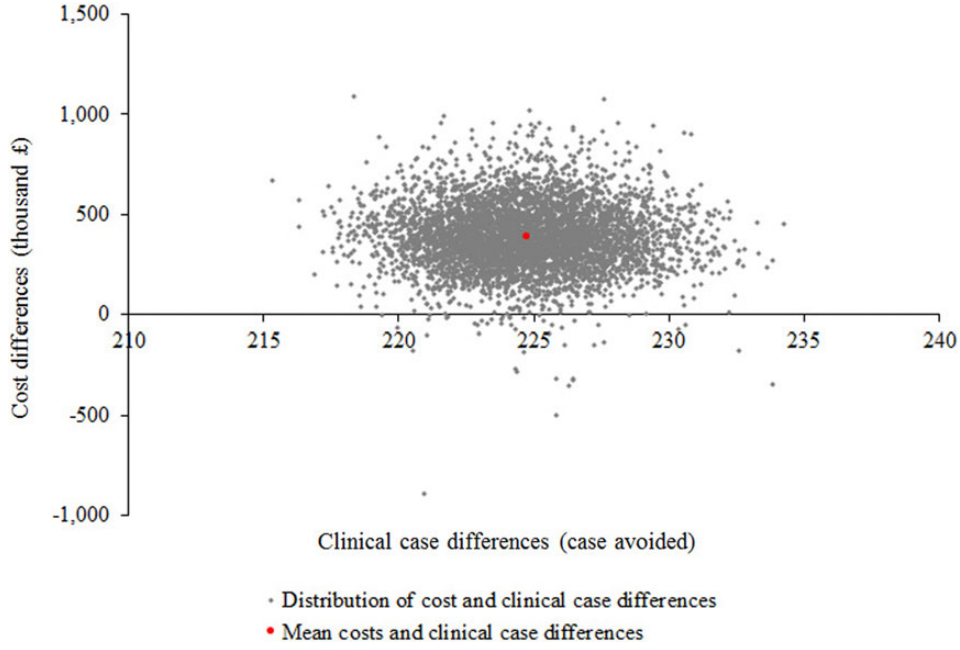

Figure 3. The distribution of incremental costs and effects in a cost-effectiveness plane for scenario in which the ward was closed after 3 days and the efficacy of the intervention was 25%.

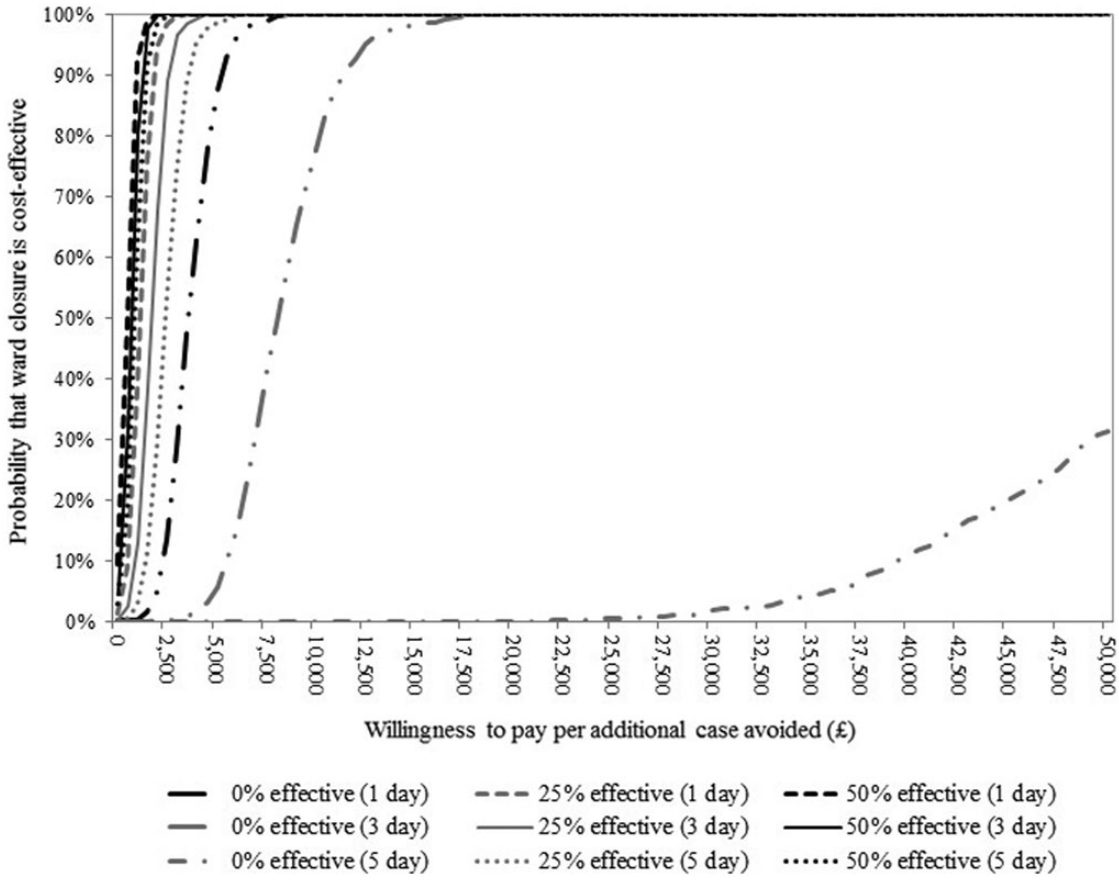

Figure 4. Cost-effectiveness acceptability curves describing the probability that each alternative ward closure option is cost-effective for a range of decision makers' willingness to pay per clinical case avoided, compared with no ward closure.

wards to new admissions increases costs to between £0.58 ($0.81) million and £1 ($1.40) million, depending on the assumed effectiveness of ward closure. The total cost does not vary much depending on the time point when a ward is closed. This is because the duration of closure is similar irrespective of when the ward is closed. Bed-day loss (due to closing wards to new patients) accounts for the largest share (65%–72%) of the total cost. Even though, on average, only 3.6 bed-days were lost for each day of unit closure to new admissions, the economic value of total bed-day loss was substantial because wards were closed for extended periods. Staff absence accounts for 28%–35% of the total cost.

Closure of wards is estimated to reduce the mean number of total outbreaks by 6%–56% and the mean number of clinical cases by 1%–55%. Ward closure leads to higher costs but reduces the number of outbreaks and clinical cases, leading to positive incremental cost-effectiveness ratios. The cost per outbreak averted varies from approximately £10 000 ($14 000) to £306 000 ($428 000), and the cost per case averted varies from about £500 ($700) to £61 000 ($85 000) (Table 3), compared with no ward closure. The currency conversion factor that was used was £1 equals $1.429 (http://www.oecd.org/std/prices-ppp/purchasingpowerparitiespppsdata.htm). Overall, both the cost per outbreak averted and the cost per case averted decrease as the efficacy of the intervention increases, and both increase as the number of days to ward closure since the first case increases.

Results of univariate (1-way) sensitivity analysis show that the cost-effectiveness is most sensitive to the number of bed-days lost per day of ward closure, followed by the cost of empty beds in general medical wards, the average duration of illness, the cost of 1 day of staff absence, the unit cost of an empty bed in an admission ward, and the unit cost of an empty bed in a long-stay ward (Figure 2). The probabilistic sensitivity analysis shows that ward closure is highly likely to increase costs to the hospital and to avert cases of nosocomial infection (Figure 3). There is a very low probability that ward closure saves costs (Figure 3).

The CEACs (Figure 4) show the sensitivity of the cost-effectiveness probability of ward closure to different valuations of case avoidance. For instance, at an assumed amount willing to pay of £5000 ($7000) for avoiding an additional nosocomial case, ward closure after 1–3 days is likely to be cost-effective (100% probability), provided the efficacy is ≥25%. At a lower amount willing to pay (eg, £2500 [$3500]), then ward closure is only likely to be cost-effective (100%) if it is more effective (50%) at preventing onward transmission to other wards. The CEACs for outbreaks avoided are presented in Supplementary Figure 2. The ward closure is cost-effective (100% probability) if the efficacy is high (50%) and the amount willing to pay to avoid an outbreak is as high as £35 000 ($49 000). The probability that ward closure is the most cost-effective option is never >10% when ward closure is not effective, irrespective of how much society is willing to pay to avoid an outbreak. This leads to us infer that the efficacy of ward closure is critical from a cost-effectiveness perspective.

DISCUSSION

A number of novel findings about the introduction, transmission, and control of norovirus in hospital settings emerge from this study. First, we found a clear relationship between norovirus activity in the community and hospital outbreaks. This suggests that importation by patients, staff, or visitors has an important role in seeding new hospital outbreaks. Second, there is significant transmission between wards: as the number of affected wards in a hospital increases, the risk of subsequent spread of the outbreak to unaffected wards increases. Third, although there are few admission wards in a hospital, they are particularly important for transmission to other parts of the hospital, presumably because of the high rate of transfers from these units. Fourth, closing a ward to new admissions on the third day of an outbreak results in an economic loss of approximately £14 000 ($19 600) but, based on fairly conservative assumptions, results in around a third fewer subsequent outbreaks and clinical cases. Fifth, ward closure is probably cost-effective at a low level of willingness to pay (eg, £2500 [$3500]) to avoid a hospital-acquired case of norovirus infection, as long as it is at least 25% efficacious at preventing transmission to other wards. The cost per outbreak shows that ward closure is cost-effective only when the efficacy is high (50%) and the amount willing to pay to avoid an outbreak exceeds £35 000 ($49 000). Sixth, the efficacy of ward closure is critical when evaluating ward closure from an economic perspective.

There are few studies of the costs of outbreaks, so estimating the cost-effectiveness of policies to control them is difficult. In addition, outbreaks are inherently stochastic, meaning that it is necessary to study a large number of these events to determine the factors associated with transmission. Our models were based on a large, prospective, active follow-up study, with >200 outbreaks recorded during the study period. Fourteen hospitals were involved in the study, so the results may be reasonably generalizable to other hospitals in the United Kingdom. Even though this was the largest surveillance study of its kind, it was not designed to estimate how effective ward closure was at preventing onward transmission to other wards. Hence, we had to assume this parameter in the epidemiological and economic analyses.

Lee et al [16] recently conducted a cost-effectiveness analysis for control of norovirus in hospital settings and concluded that ward closure was one of the least cost-effective of a number of strategies they considered. This finding may vary substantially in different healthcare systems. We have explicitly taken into account both the financial and hospital-design structures of United Kingdom NHS hospitals and used real, prospectively collected infection data. In addition, Lee et al [16] studied the

impact of ward closure on transmission within a single ward. We would not expect that ward closure would significantly alter transmission within a ward. However, we assessed the impact that such a policy might have on transmission to other wards. When looking at these wider potential benefits of ward closure, it appears to be a more attractive policy.

We only took into account the costs of staff absence and the cost of bed-days lost. Other costs, such as additional length of stay, infection control measures, and cleaning measures, were omitted, as was the knock-on effect of reducing a hospital's capacity to deliver services owing to staff absence [17]. In addition, we did not estimate the quality of life impact of norovirus infections on patients (some of whom are already frail) and staff or the potential seeding of cases from the hospital to the community and long-term care facilities. Hence, this study is likely to underestimate the costs of norovirus infection outbreaks and the cost-effectiveness of preventing them. Further work is clearly needed in this area, which can in the future be incorporated into the modeling framework presented here. In the meantime, the results of the present analysis support efforts to restrict new admissions to most hospital wards in United Kingdom hospitals.

Supplementary Data

Supplementary materials are available at http://jid.oxfordjournals.org. Consisting of data provided by the author to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the author, so questions or comments should be addressed to the author.

Notes

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Potential conflicts of interest. All authors: No reported conflicts. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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