

the lifestyle or placebo groups during the brief washout period between the DPP and DPPOS studies. The researchers, however, have stated that even when this increased incidence of diabetes was included in analysis, there was 25% risk reduction with metformin after the washout period.⁹ Even if diabetes is suppressed or delayed (2 years by metformin, compared with placebo), is it cost effective to take this drug over a decade to delay diabetes for 2 years? What can be done to increase compliance with an intensive lifestyle intervention in younger individuals so that weight loss could be maintained over a long period? And finally, whether prevention of diabetes, or maintaining lower levels of glycaemia in individuals with prediabetes, would lead to any beneficial effect on cardiovascular endpoints or mortality remains to be resolved.

Prevention of diabetes is a long and winding road. There seems to be no short cut, and a persistent and prolonged intensive lifestyle intervention seems to be the most effective mode to travel on it. However, more research needs to be done with dietary (eg, high-fibre, low-glycaemic-index foods),¹⁰ physical activity (aerobic plus resistance exercise),¹¹ and pharmaceutical (especially glucagon-like peptide-based therapies) manipulations to prevent diabetes. We need more effective drugs for those who cannot follow intensive lifestyle therapy because of infirmity. Because of the high prevalence and rapid increase in the metabolic syndrome and diabetes, there is a need to apply these findings to, and generate data from, other ethnic groups and developing countries.¹²

Anoop Misra

Department of Diabetes and Metabolic Diseases, Fortis Hospitals, New Delhi 70, India
anoopmisra@metabolicresearchindia.com

I declare that I have no conflicts of interest.

- 1 Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002; **346**: 393–403.
- 2 Crandall JP, Knowler WC, Kahn SE, et al, for the Diabetes Prevention Program Research Group. The prevention of type 2 diabetes. *Nat Clin Pract Endocrinol Metab* 2008; **4**: 382–93.
- 3 Tuomilehto J, Lindstrom J, Eriksson JG, et al, for the Finnish Diabetes Prevention Study Group. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001; **344**: 1343–50.
- 4 Hamman RF, Wing RR, Edelstein SL, et al. Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care* 2006; **29**: 2102–07.
- 5 Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M, for the STOP-NIDDM Trial Research Group. Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. *Lancet* 2002; **359**: 2072–07.
- 6 Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V, Indian Diabetes Prevention Programme (IDPP). The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). *Diabetologia* 2006; **49**: 289–97.
- 7 Walker EA, Molitch M, Kramer MK, et al. Adherence to preventive medications: predictors and outcomes in the Diabetes Prevention Program. *Diabetes Care* 2006; **29**: 1997–2002.
- 8 Diabetes Prevention Program Research Group. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcome Study. *Lancet* 2009; published online Oct 29. DOI:10.1016/S0140-6736(09)61457-4.
- 9 Diabetes Prevention Program Research Group. Effects of withdrawal from metformin on the development of diabetes in the Diabetes Prevention Program. *Diabetes Care* 2003; **26**: 977–80.
- 10 Riccardi G, Rivellese AA, Giacco R. Role of glycemic index and glycemic load in the healthy state, in prediabetes, and in diabetes. *Am J Clin Nutr* 2008; **87**: 269S–74S.
- 11 Misra A, Alappan NK, Vikram NK, et al. Effect of supervised progressive resistance-exercise training protocol on insulin sensitivity, glycemia, lipids, and body composition in Asian Indians with type 2 diabetes. *Diabetes Care* 2008; **31**: 1282–87.
- 12 Misra A, Khurana L. Obesity and the metabolic syndrome in developing countries. *J Clin Endocrinol Metab* 2008; **93** (suppl 1): S9–30.



Routine daily vs on-demand chest radiographs in intensive care

Published Online
November 5, 2009
DOI:10.1016/S0140-6736(09)61632-9
See [Articles](#) page 1687

Routine daily chest radiography is common in intubated and mechanically ventilated patients, in accord with professional society recommendations.¹ A key justification is the belief that routine chest radiographs allow prompt detection of problems that could be missed by clinical evaluation (eg, early pneumothoraces or malpositioned endotracheal tubes).²

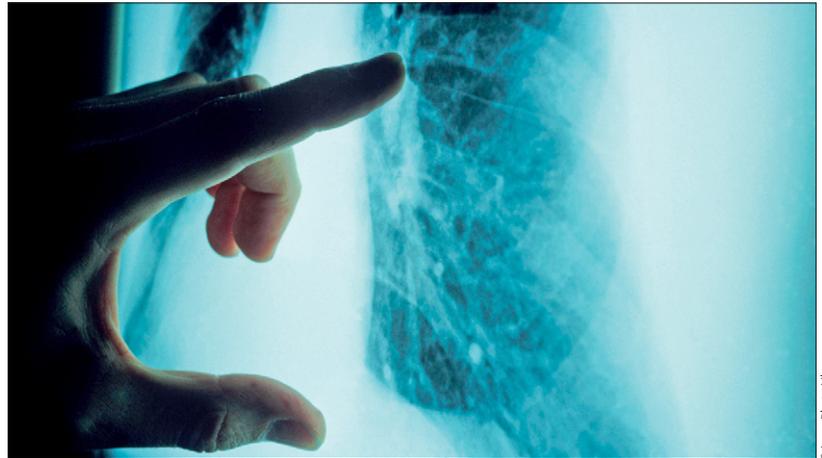
The value of routine chest radiography has been questioned for many years.^{3–5} In one study, only 5.8% of routine chest radiographs revealed unexpected findings, less than half of which required a response.⁶ Careful bedside monitoring can detect displaced endotracheal

tubes, belying the rationale for many such radiographs.^{5,7} Forgoing routine chest radiography could: save money; redirect resources; decrease radiation exposure; minimise testing for false-positive or unimportant findings; and mitigate procedure-related adverse effects, including discomfort, desaturation, and tube displacement.^{6,8–10}

Several small studies have compared the value of routine chest radiography to those done on-demand for specific indications.^{8,10–12} In a randomised study, patients managed with an on-demand strategy had fewer chest radiographs (4.4 vs 6.8).⁸ Compared with routine imaging, on-demand chest radiographs had

a higher yield: more images had new findings (53% vs 33%) and new findings requiring intervention (27% vs 13%). Another prospective controlled study showed that abandoning the routine strategy decreased the volume of chest radiographs by 35%.¹² Routine studies identified new or progressive major findings in only 4.4% and changed management in only 1.9%. In another randomised study, delayed diagnoses occurred in only 0.7% of the on-demand group and all findings were minor.⁷ In another study, after an on-demand strategy was incorporated into practice in the intensive care unit, the ratio of chest radiographs per patient-day decreased from 1.1 to 0.6.¹¹ None of these studies has identified complications associated with the on-demand approach, such as increased duration of mechanical ventilation, length of stay, or mortality.^{7,8,11,12} As a group, these investigations provide provocative if not conclusive evidence that forgoing routine chest radiography can decrease the number of procedures done, increase their yield, and potentially decrease cost and radiation exposure without compromising safety. However, no study has been powerful enough to transform practice.

In *The Lancet* today, Gilles Hejblum and colleagues describe the largest investigation to date, examining whether an on-demand strategy could safely decrease the average number of chest radiographs in mechanically ventilated patients.¹³ 21 French intensive care units participated, enrolling 424 and 425 patients in the routine and on-demand groups, respectively. Each intensive care unit served as its own control, in a cluster-randomised two-period two-strategies crossover design. Patients in the routine strategy had daily radiographs, irrespective of clinical status, whereas on-demand patients had chest radiographs only if the morning clinical examination suggested a need. The mean daily number of radiographs per patient was 1.09 in the routine group and to 0.75 in the on-demand group, which corresponded to 32% fewer radiographs. The number of chest radiographs leading to diagnostic or therapeutic interventions was similar in the two groups, making it unlikely that important abnormalities were missed. Key clinical outcomes were similar: the on-demand group had no increase in the duration of mechanical ventilation, length of stay in intensive care, or mortality. Overall the findings suggest an on-demand strategy can substantially and safely decrease the number of chest radiographs in intubated and mechanically ventilated patients.



Science Photo Library

Today's study has many strengths. It was large, representing 5% of all French intensive care units. Medical, surgical, and mixed intensive care units participated. The cluster-randomised crossover design prevented local practice style from biasing the results. Although the study was in a single country, patients resembled those managed worldwide, suggesting broad relevance. However, because all participating intensive care units were closed (ie, with patients' care directed by a dedicated intensivist-led team), extrapolation to units with different care models might not be justified.

Some unanswered questions remain. First, today's study does not tell us how long critically ill patients can safely go without a chest radiograph if no clinical indications arise. Second, the investigators did not specifically explore the potential benefit of documenting negative findings on routine studies,⁶ which could influence treatment (eg, if a finding of clear lungs would allow antibiotics to be discontinued). Third, they did not specifically study how switching from routine to on-demand studies might influence workflow and efficiency, although they did show that the number of chest radiographs obtained outside traditional morning hours did not increase significantly. Perhaps most importantly, we still do not know if certain subgroups of mechanically ventilated patients, for example those with severe acute respiratory distress syndrome, might benefit from routine chest radiography.^{4,5,7,8} Similarly, patients treated in intensive care units where clinical assessment and response might be inadequate or delayed (eg, those without full-time intensivists)¹¹ could conceivably merit routine chest radiography.

Hejblum and colleagues have provided persuasive evidence that routine daily chest radiographs are

unnecessary in most intubated and mechanically ventilated patients, and can be safely replaced by an on-demand approach, reserving studies for clinical indications. Whether an on-demand strategy is appropriate for individual intensive care units needs to be decided locally. In our view, an on-demand strategy should be adopted only if: skilled clinicians are available to promptly identify patients requiring chest radiography; images can be made and interpreted efficiently; and abnormalities can be acted on throughout the day. If these conditions are met, an on-demand strategy would seem justified and might lead to cost savings, decreased radiation exposure, and a greater diagnostic and therapeutic yield from the radiography.

*Mark D Siegel, Ami N Rubinowitz

Pulmonary & Critical Care Section, Department of Internal Medicine, Yale School of Medicine, New Haven, CT 06520, USA (MDS); and Department of Diagnostic Radiology, Yale School of Medicine, New Haven, CT, USA (ANR)
mark.siegel@yale.edu

We declare that we have no conflicts of interest.

- 1 American College of Radiology. ACR appropriateness criteria: routine chest radiograph. 2006. <http://www.dcamedical.com/webdocuments/appropriateness-criteria-routine-chest-xray.pdf> (accessed Aug 21, 2009).
- 2 Rubinowitz AN, Siegel MD, Tocino I. Thoracic imaging in the ICU. *Crit Care Clin* 2007; **23**: 539–73.
- 3 Graat M, Hendrikse K, Spronk P, Korevaar J, Stoker J, Schultz M. Chest radiography practice in critically ill patients: a postal survey in the Netherlands. *BMC Med Imaging* 2006; **6**: 8.
- 4 Hejblum G, Iloos V, Vibert J-F, et al. A web-based Delphi study on the indications of chest radiographs for patients in ICUs. *Chest* 2008; **133**: 1107–12.
- 5 Iberti TJ. Daily chest radiographs: the jury is still out. *Crit Care Med* 1991; **19**: 597.
- 6 Graat M, Choi G, Wolthuis E, et al. The clinical value of daily routine chest radiographs in a mixed medical-surgical intensive care unit is low. *Crit Care* 2006; **10**: R11.
- 7 Clec'h C, Simon P, Hamdi A, et al. Are daily routine chest radiographs useful in critically ill, mechanically ventilated patients? A randomized study. *Intensive Care Med* 2008; **34**: 264–70.
- 8 Krivopal M, Shlobin OA, Schwartzstein RM. Utility of daily routine portable chest radiographs in mechanically ventilated patients in the medical ICU. *Chest* 2003; **123**: 1607–14.
- 9 Lessnau K-D. From Delphi to knowledge and comfort. *Chest* 2008; **133**: 1060–62.
- 10 Chahine-Malus N, Stewart T, Lapinsky SE, et al. Utility of routine chest radiographs in a medical-surgical intensive care unit: a quality assurance survey. *Crit Care* 2001; **5**: 271–75.
- 11 Graat M, Kröner A, Spronk P, et al. Elimination of daily routine chest radiographs in a mixed medical-surgical intensive care unit. *Intensive Care Med* 2007; **33**: 639–44.
- 12 Hendrikse KA, Gratama JWC, ten Hove W, Rommes JH, Schultz MJ, Spronk PE. Low value of routine chest radiographs in a mixed medical-surgical ICU. *Chest* 2007; **132**: 823–28.
- 13 Hejblum G, Chalumeau-Lemoine L, Iloos V, et al. Comparison of routine and on-demand prescription of chest radiographs in mechanically ventilated adults: a multicentre, cluster-randomised, two-period crossover study. *Lancet* 2009; published online Nov 5. DOI:10.1016/S0140-6736(09)61459-8.

An affordable cholera vaccine: an important step forward

Published Online
October 9, 2009
DOI:10.1016/S0140-6736(09)61418-5
See [Articles](#) page 1694

The cholera epidemic in Zimbabwe, which has claimed over 4000 lives since August, 2008,¹ has refocused the world's attention on strategies to prevent cholera. Such devastating cholera outbreaks, increasingly common as a result of sudden movements of populations and natural disasters, represent the tip of the iceberg and add to the regular burden of endemic cholera. WHO reported 236 896 cholera cases worldwide in 2006, an increase of 79% over the previous year, although these figures are thought to represent only 5–10% of actual cases.² For regions of the world beset with endemic cholera, such as southeast Asia and eastern and northwestern Africa, better sanitary conditions and clean drinking water are the solutions for preventing seasonal cholera epidemics. However, these improvements have not taken place rapidly enough, further highlighting the growing need for a safe, effective, and affordable cholera vaccine that can be deployed in cholera-endemic regions.

In *The Lancet* today, Dipika Sur and colleagues³ report the results of a phase 3 trial of a killed oral cholera vaccine in a cholera-endemic region of India. The vaccine is a redesigned version of a proven safe⁴ and effective⁵ bivalent (contains O1 and O139 serogroups of *Vibrio cholerae*) cholera vaccine, which is produced and deployed in Vietnam. The current Indian vaccine they studied is based on the Vietnamese vaccine,⁶ but with strain changes and other modifications designed to meet WHO production standards and removal of all cholera toxin.

Today's study evaluated the redesigned vaccine for efficacy against cholera in more than 65 000 individuals, including children older than 1 year, living in an urban slum in India. The investigators randomised clusters of households to receive either two doses of the vaccine or the placebo. They report the results of a planned interim analysis of the first 2 years of follow-up. The vaccine did not increase the risk of side-effects

Comparison of routine and on-demand prescription of chest radiographs in mechanically ventilated adults: a multicentre, cluster-randomised, two-period crossover study



Gilles Hejblum, Ludivine Chalumeau-Lemoine, Vincent Ios, Pierre-Yves Boëlle, Laurence Salomon, Tabassome Simon, Jean-François Vibert, Bertrand Guidet

Summary

Background Present guidelines recommend routine daily chest radiographs for mechanically ventilated patients in intensive care units. However, some units use an on-demand strategy, in which chest radiographs are done only if warranted by the patient's clinical status. By comparison between routine and on-demand strategies, we aimed to establish which strategy was more efficient and effective for optimum patient care.

Methods In a cluster-randomised, open-label crossover study, we randomly assigned 21 intensive care units at 18 hospitals in France to use a routine or an on-demand strategy for prescription of chest radiographs during the first of two treatment periods. Units used the alternative strategy in the second period. Each treatment period lasted for the time taken for enrolment and study of 20 consecutive patients per intensive care unit; patients were monitored until discharge from the unit or for up to 30 days' mechanical ventilation, whichever was first. Units enrolled 967 patients, but 118 were excluded because they had been receiving mechanical ventilation for less than 2 days. The primary outcome measure was the mean number of chest radiographs per patient-day of mechanical ventilation. Analysis was by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00893672.

Findings 11 intensive care units were randomly allocated to use a routine strategy to order chest radiographs in the first treatment period, and 10 units to use an on-demand strategy. Overall, 424 patients had 4607 routine chest radiographs (mean per patient-day of mechanical ventilation 1.09, 95% CI 1.05–1.14), and 425 had 3148 on-demand chest radiographs (mean 0.75, 0.67–0.83), which corresponded to a reduction of 32% (95% CI 25–38) with the on-demand strategy ($p < 0.0001$).

Interpretation Our results strongly support adoption of an on-demand strategy in preference to a routine strategy to decrease use of chest radiographs in mechanically ventilated patients without a reduction in patients' quality of care or safety.

Funding Assistance Publique-Hôpitaux de Paris (Direction Régionale de la Recherche Clinique Ile de France).

Introduction

The American College of Radiology recommends routine daily chest radiographs for mechanically ventilated patients, and use of further radiographs if necessary.¹ This strategy is controversial: some clinicians are in support,^{2–8} whereas others advocate on-demand prescription of chest radiographs when warranted by the patient's clinical status.^{9–19}

Routine chest radiography has two main advantages. First, some potentially life-threatening situations that might otherwise fail to be diagnosed can be discovered and treated.^{4–6} Second, the decision to do a chest radiograph is not necessary, and in the case of restricted mobile resources for chest radiography, scheduling of the examinations during morning rounds might be more efficient. By contrast, the on-demand strategy might avoid unnecessary radiation exposure and provides substantial cost savings. Moreover, very few routine chest radiographs lead to therapeutic or diagnostic interventions.^{12,15,16} However, the consequences of the on-demand strategy on the quality of patient care are uncertain, and an increased number of

chest radiographs might be needed during the rest of the day to compensate for those not done in the morning.

Findings from a study based on the opinions of 82 physicians working in the intensive care unit have underscored the absence of consensus regarding the need for systematic daily chest radiographs for mechanically ventilated patients.⁹ Substantial variation was recorded between the physicians' opinions of whether routine chest radiographs were needed for mechanically ventilated patients with different clinical conditions. This absence of consensus results from the lack of conclusive data to guide practice. Therefore, we did a large prospective multicentre study to assess the efficiency and effectiveness of routine versus on-demand chest radiographs for optimum care of mechanically ventilated patients, using a two-period cluster-randomised design.

Methods

Intensive care units and patients

21 intensive care units for adults, all of which are part of a Paris network for such units,²⁰ participated in the study:

Lancet 2009; 374: 1687–93

Published Online
November 5, 2009
DOI:10.1016/S0140-6736(09)61459-8

See [Comment](#) page 1656

U707, Institut National de la Santé et de la Recherche Médicale, Paris, France (G Hejblum PhD, P-Y Boëlle PhD, J-F Vibert MD, Prof B Guidet MD); UMR S 707 (G Hejblum, P-Y Boëlle, J-F Vibert, Prof B Guidet) and Service de Pharmacologie (Prof T Simon MD), Faculté de Médecine Pierre et Marie Curie, Université Pierre et Marie Curie, Paris, France; Unité de Santé Publique (G Hejblum, P-Y Boëlle), Service de Réanimation (L Chalumeau-Lemoine MD, V Ios MD, Prof B Guidet), Unité de Recherche Clinique de l'Est Parisien (Prof T Simon), and Service de Physiologie (J-F Vibert), Hôpital Saint Antoine, Assistance Publique-Hôpitaux de Paris, Paris, France; and Département de Santé Publique, Hôpital Louis Mourier, Assistance Publique-Hôpitaux de Paris, Colombes, France (L Salomon MD)

Correspondence to:
Dr Gilles Hejblum, U707, Institut National de la Santé et de la Recherche Médicale (INSERM), 27 Rue Chaligny, 75571 Paris Cedex 12, France
gilles.hejblum@inserm.fr

	Median (IQR)
Beds (n)	12 (10–16)
Senior physicians (n)	4 (4–5)
Fellows (n)	2 (1–2)
Residents (n)	3 (2–4)
Nurses (n)	27 (24–37)
Nurses' aides (n)	15 (13–20)
Physiology therapist (n)	1 (1–1)
Admissions to intensive care unit (n)	589 (426–761)
Source of admission (%)	
Emergency unit and squads	59% (46–66)
Internal transfer	39% (28–48)
External transfer	3% (1–7)
Discharge (%)	
Home	6% (4–9)
Internal transfer	61% (49–65)
External transfer	14% (10–18)
Death	19% (16–22)
Types of patient (%)	
Medical	88% (81–91)
Surgical	12% (9–19)
Length of stay in intensive care (days; median)	4 (3–4)
Patients' age (years; mean)	59 (57–60)
Patients with mechanical ventilation (%)	49% (46–55)

For every characteristic, data were supplied from the 21 intensive care units as number (n), percentage, median, or mean, as indicated. Median (IQR) was then calculated across all 21 units.

Table 1: Characteristics of the 21 participating intensive care units for the year preceding the study (2006)

13 medical, two surgical, and six mixed; 17 units were located in university hospitals. These 21 closed units account for about a third of all intensive care unit beds in the Paris region (ie, Ile de France), and 5% in France. Before the study, only one intensive care unit was operating an on-demand strategy for prescription of chest radiographs; all other units were using a routine strategy.

Newly admitted adult patients were eligible for the study if they were receiving mechanical ventilation at the time of morning rounds on any day during their stay in the intensive care unit. Only patients who were mechanically ventilated for at least 2 days were included in the analyses. These patients were monitored until discharge from the intensive care unit or for up to 30 days' mechanical ventilation, whichever was first. The first patient was enrolled on Dec 21, 2006, and the last was discharged on Aug 22, 2007; global distributions of the inclusion dates in the routine and on-demand periods were similar.

The study was approved by the patients' protective committee of Saint-Antoine hospital. The committee underscored that both strategies for giving chest radiographs were standard care procedures in intensive care units. The study was also approved by the institutional review board of the Société de Réanimation

de Langue Française, and received the required legal approval from the appropriate French data protection committees. According to the French regulation on clinical research using standard care procedures,²¹ informed consent was unnecessary, and instead patients were given information about the study. This information was posted in the visitor's waiting room of every intensive care unit, and included the procedure by which the patients could access their data and confirmed that patients could refuse to participate.

Randomisation and masking

The 21 intensive care units were randomly allocated to use a routine or on-demand strategy to order chest radiographs in the first treatment period; in the second treatment period, units used the remaining strategy. Randomisation was balanced according to the number of mechanically ventilated patients treated by each unit every year, and GH generated the allocation sequence with R software.²² The study was open-label with respect to allocation concealment and masking of intervention for practical reasons.

Study design

In the routine strategy, all mechanically ventilated patients had a daily chest radiograph, irrespective of their clinical status. Such radiographs are usually done during morning rounds. In the on-demand strategy, mechanically ventilated patients were given a chest radiograph by permanent staff at morning rounds if warranted by the findings of the morning clinical examination. In both strategies, additional unscheduled chest radiographs could be requested by the permanent staff or residents at any time. We expected that the on-demand strategy would lead to fewer chest radiographs during morning rounds than the routine strategy, but this reduction could be balanced by an increase in unscheduled chest radiographs with the on-demand strategy. We tested the hypothesis that the mean number of chest radiographs per day would be lower with the on-demand strategy than with the routine strategy (null hypothesis of no difference), with no measurable change in key outcome measures to suggest reduced quality of care.

Chest radiographs not done at admission to the intensive care unit were not included in analyses. We examined the distribution of chest radiographs for a range of periods throughout the day.

In most intensive care units worldwide, all medical staff in a given unit use the same strategy to decide when to do patients' chest radiographs. For comparison of two of these strategies, a cluster-randomised design²³—in which randomisation is done at the level of the intensive care unit rather than the patient—is appropriate since the design is indicative of usual practice in the unit. However, interpretation of results could be difficult if the number of clusters is small because differences in outcome might be due to the

treatment used or to other differences between the clusters.²⁴ In an effort to overcome these problems, we used a cluster-randomised crossover design in which all participating clusters received both methods of treatment during two periods (one period for each method). The two methods were compared with a matched-pair approach;²⁵ each cluster provided an estimate of the order by which the treatment methods were given ensured that differences recorded between the routine and on-demand strategies within a given intensive care unit were not caused by the effect of switching or secular trends.

The two treatment periods were separated by a 1-week washout period during which the intensive care unit was free to choose any strategy to order chest radiographs. Each treatment period ended either when the last mechanically ventilated patient to remain in the intensive care unit was extubated, or up to 30 days after enrolment of the last mechanically ventilated patient to remain in the unit.

We planned to recruit the same number of patients from every intensive care unit to better account for variability between units. Consequently, the duration of the study varied between units dependent on baseline recruitment and case-mix.

The primary outcome measure was the mean number of chest radiographs per patient-day of mechanical ventilation. This outcome was calculated for every patient as the ratio of the total number of radiographs to duration of mechanical ventilation. The mean was then calculated across all 21 intensive care units and for both treatment periods. The reason for doing each chest radiograph was recorded, along with any new findings leading to diagnostic procedures or therapeutic interventions. During monitoring, chest radiographs recorded in patients' report forms were checked against the local picture archiving and communication system, which was available in 20 of the 21 intensive care units. We also assessed key secondary outcome measures: days of mechanical ventilation, length of stay in the intensive care unit, and mortality of patients during their stay in the unit.

Statistical analysis

We calculated the number of patients needed to provide 80% statistical power to show a 20% difference between routine and on-demand strategies for use of chest radiographs in a bilateral test with a type 1 error of 5% (webappendix p 1). This calculation took into account the matched-pair design and correlation between patients in a given intensive care unit. The clinical type values used for the sample size calculation were based on previous annual reports of the Cub-Rea network. With 20 participating intensive care units and a mean of 1.2 (SD 0.55) chest radiographs per patient-day during the routine strategy, 100 patients (5 patients per intensive

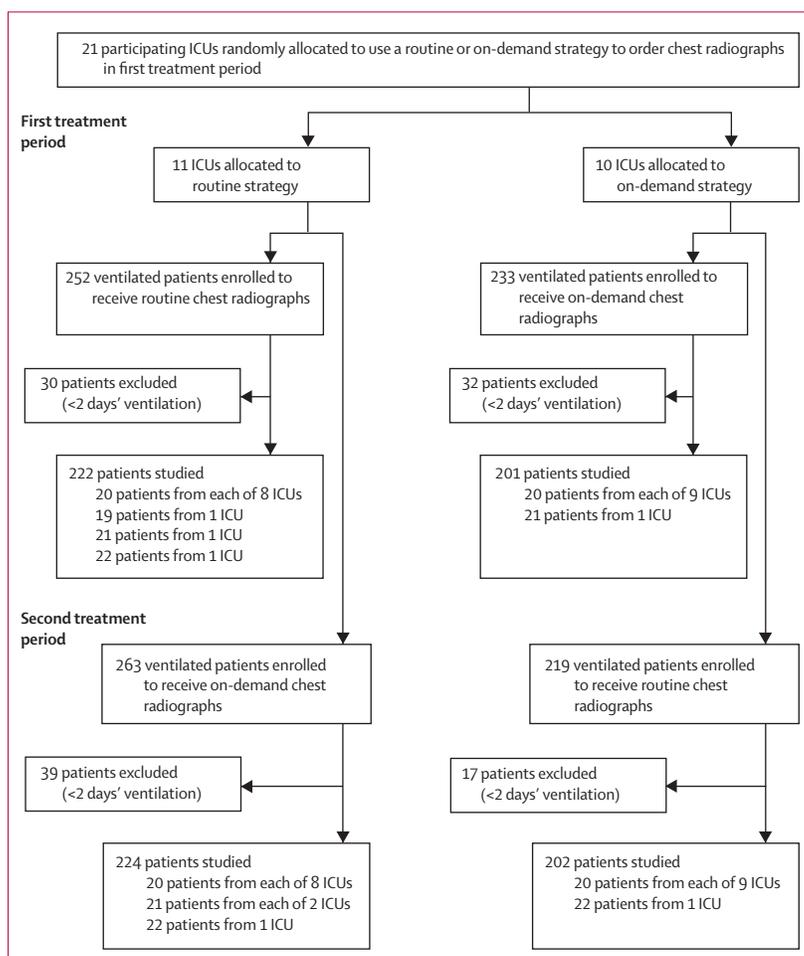


Figure 1: Study profile

Overall 424 patients (222 from 11 intensive care units, 202 from 10 units) received routine chest radiographs, and 425 (201 from 10 units, 224 from 11 units) received on-demand chest radiographs. Target study size was 840 patients, but since patient eligibility was only known 2 days after inclusion, an additional nine patients were included before the count of 20 eligible patients was reached. ICU=intensive care unit.

care unit) would have to be enrolled in each strategy to detect a difference of 20% ($\delta=1.2 \times 0.2$), in a bilateral test with a type 1 error of 5% and a power of 80%. To detect substantial differences in mortality or mean duration of mechanical ventilation, we decided that every intensive care unit would enrol 20 patients for each strategy, which was equivalent to a total of 800 patients. With a type 1 error of 5% and statistical power of 80%, such a sample size would detect a difference of 10% in mortality (we postulated that baseline mortality would be 33%), and a difference of 3 days in mean duration of mechanical ventilation (we postulated for mechanical ventilation SD 15.3) between strategies.

Analysis was by intention to treat. We compared the mean number of chest radiographs per patient-day between the two strategies using a paired *t* test. A permutation test²⁶ was used to calculate *p* values (webappendix p 2) for all comparisons between the two strategies except for two cases. First, a Wilcoxon-Mann-

See Online for webappendix

Whitney test was used to assess if the difference in chest radiographs per patient-day in a given intensive care unit between the routine and on-demand strategies was dependent on the strategy applied during the first treatment period. Second, the difference in mortality between the two strategies was tested with the Mantel-Haenszel χ^2 test stratified by intensive care unit. Simplified acute physiology score II of patients and corresponding predicted hospital mortality were assessed according to Le Gall and colleagues.²⁷ R statistical software (version 2.9.0) was used for all analyses.²²

This study is registered with ClinicalTrials.gov, number NCT00893672.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Table 1 shows characteristics of the 21 participating intensive care units. None of the participating units cared for neurosurgery or cardiac surgery patients, but all other types of patients are represented in the patient sample. Overall and in order, the ten most common diagnoses of patients admitted to the units in 2006 were: acute respiratory failure without underlying pulmonary disease, coma, septic shock, acute kidney failure, acute respiratory failure with underlying pulmonary disease, pulmonary oedema, cardiac arrest, acute respiratory distress syndrome, haemorrhagic shock, and need for postoperative care. Because of differences in the case-mix and total number of beds, the study duration was a median of 131 days (IQR 107–173) in a given intensive care unit.

Figure 1 shows the study profile. Overall, 425 patients were assigned to have chest radiographs by a routine strategy and 424 by an on-demand strategy. Table 2 shows patient characteristics at baseline. 7755 chest radiographs were done during both treatment periods under both strategies (table 3). The mean number of chest radiographs per patient-day of ventilation was significantly lower with the on-demand strategy than the routine strategy (table 3), which corresponded to a decrease of 32% (95% CI 25–38).

The range of mean numbers of chest radiographs per patient-day in the 21 intensive care units was 0.85–1.24 with the routine strategy, and 0.48–1.08 with the on-demand strategy (figure 2 and webappendix p 3). Despite this large variability, the on-demand strategy was associated with fewer chest radiographs than was the routine strategy in all 21 intensive care units (figure 2). The size of this decrease was not dependent on the

	Routine strategy (n=424)	On-demand strategy (n=425)
Age (years)	61 (51–74)	63 (49–74)
SAPS II score; predicted hospital mortality*	52 (40–66); 51.0%	52 (39–66); 51.6%
Men	257 (61%)	271 (64%)
Reason for starting mechanical ventilation		
Thoracic diseases	171 (40%)	153 (36%)
ARDS or ALI	55 (32%)	46 (30%)
Pneumonia (without ARDS or ALI criteria)	42 (25%)	34 (22%)
Acute respiratory failure with chronic respiratory insufficiency	29 (17%)	47 (31%)
Cardiogenic oedema	14 (8%)	11 (7%)
Acute respiratory failure with immunodeficiency	17 (10%)	6 (4%)
Acute asthma	7 (4%)	1 (1%)
Other	7 (4%)	8 (5%)
Extrathoracic diseases	209 (49%)	228 (54%)
Shock	104 (50%)	106 (46%)
Coma (excluding coma due to intoxication)	64 (31%)	80 (35%)
Coma due to intoxication	34 (16%)	35 (15%)
Other	7 (3%)	7 (3%)
Postoperative care	42 (10%)	41 (10%)
Unknown	2 (1%)	3 (1%)

Data are median (IQR), percentage, or number (%). SAPS II=simplified acute physiology score II. ARDS=acute respiratory distress syndrome. ALI=acute lung injury. *Percentage derived from the mean of all patients' probabilities of predicted hospital mortality, therefore number of patients is not given.

Table 2: Patient characteristics at baseline

	Routine strategy (n=424)	On-demand strategy (n=425)	p value
Chest radiographs per patient-day of mechanical ventilation (total number; mean [95% CI])*	4607; 1.09 (1.05–1.14)	3148; 0.75 (0.67–0.83)	<0.0001
Morning rounds†	3779; 0.90 (0.86–0.93)	2224; 0.54 (0.47–0.60)	<0.0001
Unscheduled‡	780; 0.18 (0.15–0.22)	893; 0.20 (0.16–0.25)	0.24
Days of mechanical ventilation (total number; mean [SD]; median [IQR])*	4172; 9.82 (8.24); 7 (4–13)	4226; 9.94 (8.75); 7 (3–14)	0.90
Length of stay (days; mean [SD]; median [IQR])	13.96 (11.61); 10 (5–19)	13.21 (11.01); 10 (5–19)	0.28
Mortality	131 (31%)	136 (32%)	0.79

Data are number (%) unless otherwise indicated. *Data were censored to 30 days of mechanical ventilation; patients with more than 30 days of mechanical ventilation were regarded as having 30 days of mechanical ventilation in all calculations. †For 48 chest radiographs done for patients on the routine strategy and 31 done for those on the on-demand strategy (p=0.9), whether the chest radiograph was done during the morning round or was unscheduled was not recorded.

Table 3: Number of chest radiographs, length of stay, duration of mechanical ventilation, and mortality in intensive care units

strategy allocated for the first treatment period ($p=0\cdot20$). The reduction was 10–56% across the 21 units: 10–20% in five centres, 20–40% in 11 centres, and more than 40% in five centres (figure 2).

The difference in the total number of routine and on-demand chest radiographs was not significant when the analysis was restricted to chest radiographs with new findings that led or contributed to diagnostic procedures or therapeutic interventions. 728 routine chest radiographs led or contributed to 824 therapeutic or diagnostic interventions in 264 patients, whereas 729 on-demand chest radiographs led or contributed to 834 interventions in 265 patients ($p=0\cdot77$). The types of interventions done were similar between strategies, except for change in ventilator settings (figure 3).

Table 3 and webappendix p 4 indicate that the on-demand strategy was associated with a large and significant decrease in chest radiographs during morning rounds, with a small increase in unscheduled chest radiographs that was not significant. Importantly, no change was recorded in any secondary outcome measures—days of mechanical ventilation, length of stay in the intensive care unit, or mortality—between the routine and on-demand strategies (table 3).

Discussion

Results from our study show a substantial reduction in use of chest radiographs with the on-demand strategy in all 21 participating intensive care units, corresponding to a 32% decrease overall compared with the routine strategy. Between the strategies, we recorded similar numbers of chest radiographs that led or contributed to therapeutic or diagnostic interventions, duration of mechanical ventilation and stay in the intensive care unit, and mortality.

We noted that although the routine protocol specified that a chest radiograph should be done at morning rounds every day, 393 (9%) fewer chest radiographs were done at morning rounds than were patient-days available. However, had routine chest radiographs been done for every day of mechanical ventilation, the difference in the number of chest radiographs between the two strategies would have been greater than our results have shown.

Six studies have compared routine and on-demand strategies: one in a cardiothoracic ward for patients after intensive care,¹¹ one in a paediatric intensive care unit,¹⁷ and four in mixed intensive care units.^{10,12,13,16} Three studies included any patients from intensive care units,^{11–13} and three focused on intubated patients only.^{10,16,17} All these single-centre studies favoured the on-demand strategy, but only two—of 519 chest radiographs in 94 patients¹⁶ and 977 chest radiographs in 165 patients¹⁰—specifically focused on adult patients who had been mechanically ventilated for at least 2 days. Our study of 7755 chest radiographs in almost 850 patients has strengths compared with previous

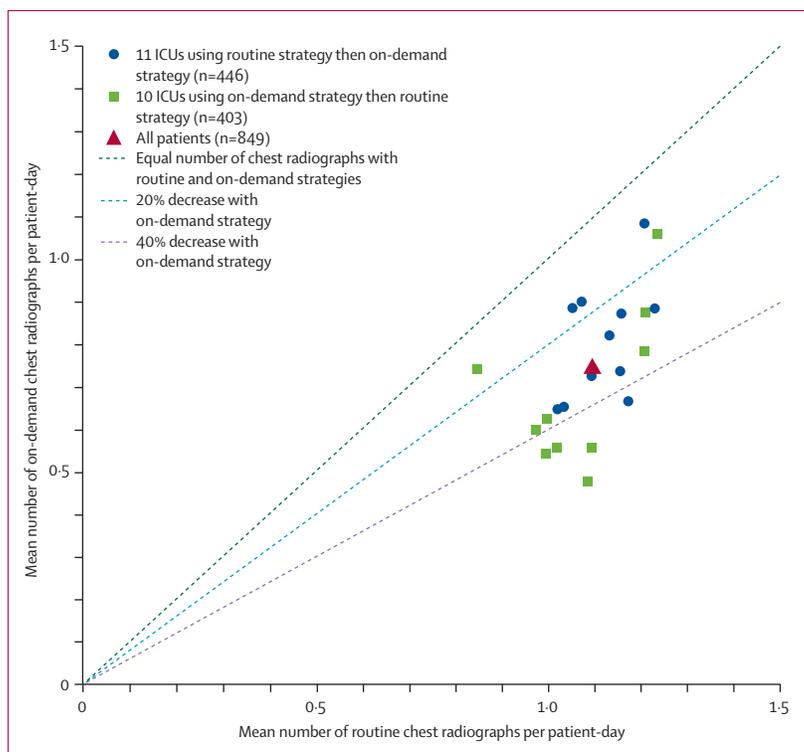


Figure 2: Mean number of routine or on-demand chest radiographs per patient-day in the 21 participating intensive care units (ICUs)

Dotted lines indicate threshold values against which data can be compared.

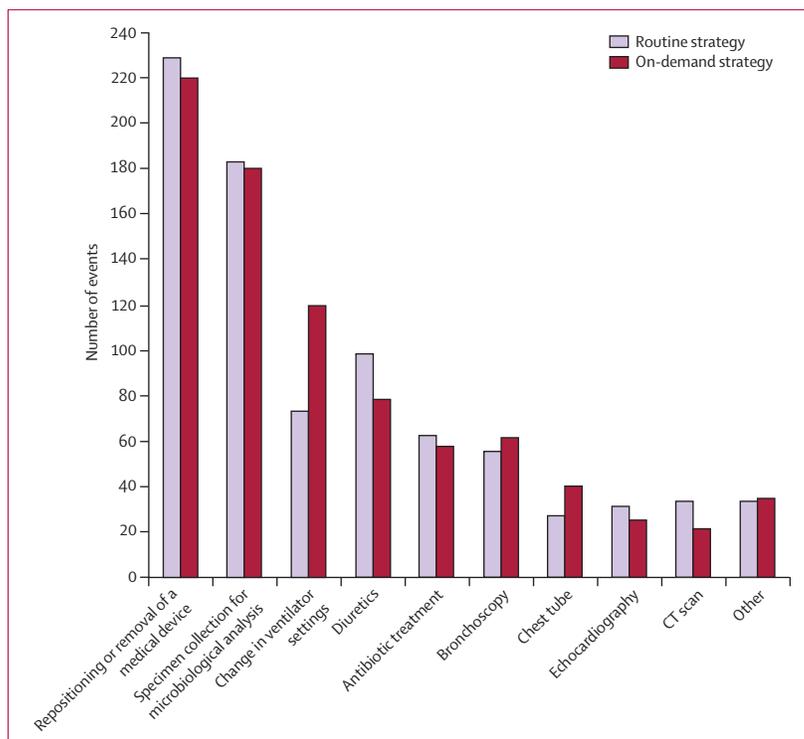


Figure 3: Distribution of diagnostic procedures or therapeutic interventions done after findings from chest radiographs

reports. Notably, our study was multicentre and the cluster-randomised crossover design accounted for variation between the intensive care units. In the 21 intensive care units, the mean decrease of 32% in chest radiographs with the on-demand strategy is in keeping with that reported from results of single-centre studies: 35%,¹⁶ 45%,¹³ 35%,¹² and 39%,¹¹ although one study showed a reduction of 90%.¹⁰

Our study is limited by the fact that routine chest radiographs are done to ensure that important findings are not missed; as underscored by Lessnau,²⁸ many intensivists are not yet comfortable with obtaining fewer chest radiographs in the absence of extensive published evidence. Although we did not investigate whether the on-demand strategy was associated with missed findings that resulted in adverse events or delay in treatment, we did show that the on-demand strategy did not change the number of chest radiographs that led or contributed to diagnostic or therapeutic interventions, duration of mechanical ventilation or stay in intensive care unit, or mortality.

Second, opinions from medical personnel participating in the study about the routine versus on-demand strategies were not recorded before, during, and after the study. This information is potentially important—for example, the physicians' workloads are increased by individual assessment of every patient early in the morning to decide whether a chest radiograph is necessary instead of ordering systematic morning chest radiographs for all mechanically ventilated patients. Such considerations could restrict implementation of the on-demand strategy in daily practice. Third, results were obtained in closed intensive care units in France, which have a specific organisation and patient case-mix (webappendix p 5). Therefore, extrapolation to different settings with other case-mix or management should be done with caution. Nevertheless, our results can be generalised to many general intensive care units sharing similar characteristics to the intensive care units included in our study.

Results from our study strongly support the adoption of an on-demand strategy in preference to a routine strategy to decrease the number of chest radiographs done in mechanically ventilated adult patients without a reduction in patient safety. In view of the large number of patients who undergo mechanical ventilation, these results could substantially benefit clinical practice.

Contributors

GH, VI, P-YB, LS, and BG designed the study and prepared the study grant application. LC-L coordinated the participating centres. TS managed all logistical aspects of the research, including budget and data monitoring. J-FV authored the software used to enter study data and prepared specific templates; GH managed data, analysed data with P-YB, and drafted the report. BG enrolled intensive care units, and initiated and coordinated the research project. All authors reviewed the draft report and approved submission of the report.

Steering Committee

M Blery (Assistance Publique-Hôpitaux de Paris, Hôpital de Bicêtre, Le Kremlin Bicêtre), P Y Boëlle (INSERM, U707, Paris), M Brauner (Assistance Publique-Hôpitaux de Paris, Hôpital Avicenne, Bobigny),

F Brivet (Assistance Publique-Hôpitaux de Paris, Hôpital Antoine Bécélère, Clamart), S Dechambine (Assistance Publique-Hôpitaux de Paris, Direction de la Politique Médicale, Paris), J Devaquet (Assistance Publique-Hôpitaux de Paris, Hôpital Henri Mondor, Créteil), N Deye (Assistance Publique-Hôpitaux de Paris, Hôpital Fernand Widal, Paris), J L Diehl (Assistance Publique-Hôpitaux de Paris, Hôpital Européen Georges Pompidou, Paris), E Fery-Lemonnier (Assistance Publique-Hôpitaux de Paris, Direction de la Politique Médicale, Paris), B Guidet (Assistance Publique-Hôpitaux de Paris, Hôpital Saint-Antoine, Paris), G Hejblum (INSERM, U707, Paris), J Holstein (Assistance Publique-Hôpitaux de Paris, Direction de la Politique Médicale, Paris), V Ioos (Assistance Publique-Hôpitaux de Paris, Hôpital Saint-Antoine, Paris), J D Laredo (Assistance Publique-Hôpitaux de Paris, Hôpital Lariboisière, Paris), C E Luyt (Assistance Publique-Hôpitaux de Paris, Groupe Hospitalier Pitié-Salpêtrière, Paris), S Maître (Assistance Publique-Hôpitaux de Paris, Hôpital Antoine Bécélère, Clamart), C Montagnier-Petrissans (Assistance Publique-Hôpitaux de Paris, Direction de la Politique Médicale, Paris), L Salomon (Assistance Publique-Hôpitaux de Paris, Direction de la Politique Médicale, Paris), E Schouman-Claeys (Assistance Publique-Hôpitaux de Paris, Hôpital Bichat, Paris), J F Vibert (INSERM, U707, Paris), M Wolff (Assistance Publique-Hôpitaux de Paris, Hôpital Bichat, Paris).

Participating centres

The 18 hospitals with 21 participating intensive care units are listed below with the head of the unit and corresponding physician for the study.

Paris Bichat: B Régnier, B Mourvillier; Cochin: J P Mira, A Cariou; Européen Georges Pompidou: J Y Fagon, J L Diehl; Lariboisière: F Baud, N Deye; Pitié-Salpêtrière (two units): J Chastre, C E Luyt, and T Similowski, A Duguet; Saint-Joseph: J Carlet, O Hamzaoui; Saint-Louis (two units): B Schlemmer, G Thiery, and B Eurin, L Jacob; Saint-Antoine: G Offenstadt, L Chalumeau-Lemoine; Tenon (two units): C M Mayaud, M Fartoukh, and F Bonnet, J P Fulgencio. *Bondy* Jean Verdier: G Dhonneur, L Tual. *Boulogne-Billancourt* Ambroise Paré: A Vieillard Baron, C Charron. *Corbeil-Essonnes* Centre Hospitalier Sud-Francilien: D Caen, P Meyer. *Colombes* Louis Mourier: D Dreyfus, J D Ricard. *Créteil* Henri Mondor: C Brun-Buisson, J Devaquet. *Garches* Raymond Poincaré: D Annane, D Orlikowski. *Le Chesnay* André Mignot: J P Bedos, N Abbosh. *Le Kremlin-Bicêtre* Bicêtre: C Richard, N Anguel. *Saint-Denis* Delafontaine: F Fraisse, M Thuong.

Conflicts of interest

We declare that we have no conflicts of interest.

Acknowledgments

We thank the research clinical assistants, and especially Louise Anemet, Linda Gimeno, Xavier Lepage; the radiology departments of the 18 hospitals participating in the study; and David Young for editorial assistance. This study was funded by a grant (SCR06006) devoted to research on standard care procedures from Assistance Publique-Hôpitaux de Paris (Direction Régionale de la Recherche Clinique Ile de France).

References

- 1 American College of Radiology. Appropriateness criteria: routine chest radiograph (2006). http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria/pdf/ExpertPanelonThoracicImaging/RoutineChestRadiographDoc7.aspx (accessed Sept 8, 2009).
- 2 Chahine-Malus N, Stewart T, Lapinsky SE, et al. Utility of routine chest radiographs in a medical-surgical intensive care unit: a quality assurance survey. *Crit Care* 2001; **5**: 271–75.
- 3 Marik PE, Janower ML. The impact of routine chest radiography on ICU management decisions: an observational study. *Am J Crit Care* 1997; **6**: 95–98.
- 4 Henschke CI, Yankelevitz DF, Wand A, Davis SD, Shiao M. Chest radiography in the ICU. *Clin Imaging* 1997; **21**: 90–103.
- 5 Brainsky A, Fletcher RH, Glick HA, Lanken PN, Williams SV, Kundel HL. Routine portable chest radiographs in the medical intensive care unit: effects and costs. *Crit Care Med* 1997; **25**: 801–05.
- 6 Hall JB, White SR, Karrison T. Efficacy of daily routine chest radiographs in intubated, mechanically ventilated patients. *Crit Care Med* 1991; **19**: 689–93.
- 7 Bekemeyer WB, Crapo RO, Calhoun S, Cannon CY, Clayton PD. Efficacy of chest radiography in a respiratory intensive care unit. A prospective study. *Chest* 1985; **88**: 691–96.

- 8 Greenbaum DM, Marschall KE. The value of routine daily chest x-rays in intubated patients in the medical intensive care unit. *Crit Care Med* 1982; **10**: 29–30.
- 9 Hejblum G, Ioos V, Vibert JF, et al. A web-based Delphi study on the indications of chest radiographs for patients in ICUs. *Chest* 2008; **133**: 1107–12.
- 10 Clec'h C, Simon P, Hamdi A, et al. Are daily routine chest radiographs useful in critically ill, mechanically ventilated patients? A randomized study. *Intensive Care Med* 2008; **34**: 264–70.
- 11 Mets O, Spronk PE, Binnekade J, Stoker J, de Mol BA, Schultz MJ. Elimination of daily routine chest radiographs does not change on-demand radiography practice in post-cardiothoracic surgery patients. *J Thorac Cardiovasc Surg* 2007; **134**: 139–44.
- 12 Hendrikse KA, Gratama JW, Hove W, Rommes JH, Schultz MJ, Spronk PE. Low value of routine chest radiographs in a mixed medical-surgical ICU. *Chest* 2007; **132**: 823–28.
- 13 Graat ME, Kroner A, Spronk PE, et al. Elimination of daily routine chest radiographs in a mixed medical-surgical intensive care unit. *Intensive Care Med* 2007; **33**: 639–44.
- 14 Graat ME, Hendrikse KA, Spronk PE, Korevaar JC, Stoker J, Schultz MJ. Chest radiography practice in critically ill patients: a postal survey in the Netherlands. *BMC Med Imaging* 2006; **6**: 8.
- 15 Graat ME, Choi G, Wolthuis EK, et al. The clinical value of daily routine chest radiographs in a mixed medical-surgical intensive care unit is low. *Crit Care* 2006; **10**: R11.
- 16 Krivopal M, Shlobin OA, Schwartzstein RM. Utility of daily routine portable chest radiographs in mechanically ventilated patients in the medical ICU. *Chest* 2003; **123**: 1607–14.
- 17 Price MB, Grant MJ, Welkie K. Financial impact of elimination of routine chest radiographs in a pediatric intensive care unit. *Crit Care Med* 1999; **27**: 1588–93.
- 18 Bhagwanjee S, Muckart DJ. Routine daily chest radiography is not indicated for ventilated patients in a surgical ICU. *Intensive Care Med* 1996; **22**: 1335–38.
- 19 Fong Y, Whalen GF, Hariri RJ, Barie PS. Utility of routine chest radiographs in the surgical intensive care unit. A prospective study. *Arch Surg* 1995; **130**: 764–68.
- 20 Luyt CE, Combes A, Aegerter P, et al. Mortality among patients admitted to intensive care units during weekday day shifts compared with “off” hours. *Crit Care Med* 2007; **35**: 3–11.
- 21 Lemaire F, Schortgen F, Chastre J, et al. Nouvelle législation portant sur les soins courants : rappel des difficultés passées. *Presse Med* 2007; **36**: 1167–73.
- 22 R Development Core Team. R: a language and environment for statistical computing. Vienna: R Foundation for Statistical Computing, 2008.
- 23 Donner A, Klar N. Design and analysis of cluster randomization trials in health research. London: Hodder Arnold, 2000.
- 24 Turner RM, White IR, Croudace T. Analysis of cluster randomized cross-over trial data: a comparison of methods. *Stat Med* 2007; **26**: 274–89.
- 25 Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials* 2007; **28**: 182–91.
- 26 Good P. Permutation, parametric and bootstrap tests of hypotheses, 3rd edn. New York, NY: Springer, 2004.
- 27 Le Gall JR, Lemeshow S, Saulnier F. A new simplified acute physiology score (SAPS II) based on a European/North American multicenter study. *JAMA* 1993; **270**: 2957–63.
- 28 Lessnau KD. From Delphi to knowledge and comfort: the devil is in the details. *Chest* 2008; **133**: 1060–62.