

# Mortality reduction in cardiac anesthesia and intensive care: results of the first International Consensus Conference

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*HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2011; 3: 9-19*

## ABSTRACT

**Background:** There is no consensus on which drugs/techniques/strategies can affect mortality in the peri-operative period of cardiac surgery. With the aim of identifying these measures, and suggesting measures for prioritized future investigation we performed the first international consensus conference on this topic.

**Methods:** The consensus was a continuous international internet-based process with a final meeting on June 28th 2010 in Milan at the Vita-Salute University. Participants included 340 cardiac anesthesiologists, cardiac surgeons and cardiologists from 65 countries all over the world. A comprehensive literature review was performed to identify topics that subsequently generated position statements for discussion, voting and ranking.

**Results:** Of the 17 major topics with a documented mortality effect, seven were subsequently excluded after further evaluation due to concerns about clinical applicability and/or study methodology. The following topics are documented as reducing mortality: administration of insulin, levosimendan, volatile anesthetics, statins, chronic beta-blockade, early aspirin therapy, the use of preoperative intra-aortic balloon counterpulsation and referral to high-volume centers. The following are documented as increasing mortality: administration of aprotinin and aged red blood cell transfusion. These interventions were classified according to the level of evidence and effect on mortality and a position statement was generated.

**Conclusion:** This international consensus conference has identified the non-surgical interventions that merit urgent study to achieve further reductions in mortality after cardiac surgery: insulin, intra-aortic balloon counterpulsation, levosimendan, volatile anesthetics, statins, chronic beta-blockade, early aspirin therapy, and referral to high-volume centers. The use of aprotinin and aged red blood cells may result in increased mortality.

**Keywords:** *anesthesia, intensive care, cardiac anesthesia, cardiac surgery, mortality, cardiopulmonary bypass, consensus development conference, treatment outcome, focused update, prevention and control.*

This paper is co-published in "Acta Anaesthesiologica Scandinavica" and "HSR Proceedings in Intensive Care and Cardiovascular Anesthesia" in the year 2011

## INTRODUCTION

Every year over one million patients worldwide undergo cardiac surgery (1) and are exposed to significant morbidity and mortality.

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Many drugs, techniques and management strategies have been used in an attempt to reduce this mortality.

Currently no consensus exists as to their effect either positive or negative on patient mortality.

The goal of this first International Consensus Conference was to identify these ancillary (i.e. non-surgical) interventions; to quantify their impact either positive or negative on all-cause mortality in cardiac surgery; and then to make suggestions to both researchers and donors as to which topics deserve further investigation in the immediate future.

## METHODS

Cardiac anaesthesiologists, cardiac surgeons, and cardiologists participated in person, through email or through the congress website.

In the period May 2008 – June 2010 a core group of experts in the field undertook a comprehensive review of the published evidence related to the prevention of perioperative mortality in cardiac anesthesia and intensive care.

Each participant suggested one or more topics of interest and submitted them electronically together with one or more articles published in peer-reviewed journals supporting their opinion.

Over 100 international anesthesiology and cardiac surgery scientific societies were contacted and asked to disseminate information about the Consensus Conference (either via email or by means of website links) to allow their authoritative representatives to participate. All journals with an impact factor in the fields of Anesthesiology, Critical Care Medicine, Cardiac and Cardiovascular Systems were contacted and asked to suggest seminal papers to be included in the Consensus Conference.

Over 50 patient and nurse associations

were contacted via email and asked to disseminate information about the conference to their members.

The following PubMed search strategy (updated on June 28<sup>th</sup> 2010) was used to systematically identify related topics: systematic[sb] AND (surgery[tiab] OR surgic\*[tiab] OR operation\*[tiab]) AND ((myocardial AND infarction) OR (death\* OR survival OR mortality OR prognosis)) AND (prevent\* OR reducti\* OR reduci\*).

Participants were asked to suggest topics with the following inclusion criteria:

- a) a study published in a peer-reviewed journal;
- b) including ancillary (i.e. non-surgical) treatments (drug/technique/strategy) in patients undergoing cardiac surgery;
- c) with a statistically significant reduction/increase in mortality.

Only studies that fulfilled all these criteria were accepted as valid for study inclusion. Between June 20<sup>th</sup> to June 28<sup>th</sup> 2010, a web site allowed participants the opportunity to vote in support of or against the suggested topics or to suggest new topics, as well as the opportunity to produce scientific articles in support of the different drugs/techniques/strategies. Specific aims of the Consensus Conference were to establish whether:

- a) the most recent evidence had been collected;
- b) the reduction or increase in mortality was supported by either: randomized controlled trials or meta-analyses of randomized controlled trials, case-matched studies, meta-analyses of case matched studies, or other studies;
- c) the evidence had been derived from a subgroup or a primary analysis;
- d) the evidence had been derived entirely or partially from cardiac-surgical population; and when among a cardiac surgical population, if it was applicable to every cardiac intervention or to certain subgroups only;

**Table 1** - Ten major ancillary (i.e. non-surgical) drugs/techniques/strategies that might influence survival rates in patients undergoing cardiac surgery and are presented here in order of level of evidence-base-medicine together with the percentage of agreement that was reached among the participant of the Consensus Conference.

Author (year)	% of agreement first vote	% of agreement second vote	Drug Technique Strategy	Effect on mortality	Final statement
<b>Randomized Controlled Trials</b>					
Van den Berghe G (2001) <sup>2</sup>	62%	80%	Insulin	Reduction	A single centre randomized study demonstrated that maintaining tight glycemic control with a continuous insulin infusion can reduce mortality in intensive care in critically ill patients, including post-cardiac surgery patients. However, we recommend caution when using this technique as studies in non-cardiac surgery populations have found hypoglycemic episodes resulting in increased mortality.
Fergusson DA (2008) <sup>3</sup>	44%	65%	Aprotinin	Increase	Despite the possibility of a reduction in massive bleeding, aprotinin increases 30-day mortality in patients undergoing cardiac surgery.
<b>Meta-analyses of Randomized Controlled Trials</b>					
Field ML (2007) <sup>4</sup>	56%	85%	Intra-Aortic balloon pump	Reduction	Pre-operative IABP might reduce 30-day mortality in elective high risk patients undergoing CABG unless specifically contraindicated.
Landoni G (2010) <sup>5</sup>	61%	77%	Levosimendan	Reduction	In a meta-analysis of pooled pre- and post-operative administration, levosimendan seems to reduce 30-day mortality. However, there is not enough evidence to recommend its routine administration since statistical significance is lost when data are evaluated separately. Caution is advised in bolus administration.
Landoni G (2007) <sup>6</sup>	56%	75%	Volatile anaesthetics	Reduction	Volatile anaesthetics might reduce 30-day mortality in hemodynamically stable patients undergoing CABG, as documented by a meta-analysis of RCTs.
<b>Meta-analyses including non-Randomized Controlled Trials</b>					
Takagi H (2009) <sup>7</sup>	59%	80%	Statins	Reduction	A meta-analysis of mostly non-RCTs in CABG suggested a postoperative all-cause mortality reduction in patients receiving pre-operative statins. This topic merits further investigation.
<b>Non randomized studies</b>					
Ferguson TB Jr (2002) <sup>8</sup>	78%	94%	Chronic $\beta$ -blocker usage	Reduction	Data from a large cohort study suggest that patients without severe (EF < 30%) LV dysfunction who are on pre-operative beta blockers have a reduced 30-day mortality after CABG surgery. . Therefore beta blockers should not be discontinued prior to CABG in these patients.

Author (year)	% of agreement first vote	% of agreement second vote	Drug Technique Strategy	Effect on mortality	Final statement
Mangano DT (2002) <sup>9</sup>	63 %	87 %	Early-aspirin usage	Reduction	Early (6-48h) use of aspirin after CABG, unless specifically contraindicated, is safe and might be associated with a reduction in in-hospital mortality. The evidence comes from a non RCT.
Birkmeyer JD (2003) <sup>10</sup>	52 %	74 %	High-volume surgeon	Reduction	Thirty-day mortality in cardiac surgery appears to be related to surgeon volume. The evidence comes from non-randomized observation and probably pertains to the whole surgical team.
Koch CG (2008) <sup>11</sup>	64 %	77 %	Old red blood cell transfusions	Increase	A large non-RCT suggests that transfusion of packed red blood cells stored for more than 15 days is associated with an increase of in-hospital and 1-year mortality.

## Abbreviations

RCT: Randomized controlled trial; IABP: Intra-aortic balloon pump; CABG: Coronary artery bypass grafting; EF: Ejection fraction; LV: Left ventricle

- e) the drug/technique/strategy was used in the operative room or in an intensive care unit;
- f) mortality was the endpoint, or mortality was included in a composite endpoint.

The Consensus was a continuous interactive web-based process, with the main, final meeting held on June 28<sup>th</sup> 2010 at the Vita-Salute University of Milan, Italy when all 120 suggested topics were discussed.

Major and minor topics were identified according to the presence or not of at least one article showing a statistically significant reduction/increase in mortality.

After a presentation from both a rapporteur and a co-rapporteur a short statement was drawn up for each major topic describing the reasons for it being considered as providing convincing (*Table 1*), or non convincing (*Table 2*) evidence.

Thus, for each convincing major topic the Consensus Conference approved a position statement, and highlighted the appropriate peer-reviewed published evidence.

Final statements were created, discussed

and corrected during the conference and later on exposed to the judgment of all the web participants: from June 29<sup>th</sup> to September 30<sup>th</sup> 2010 participants were asked to support or challenge the findings and statements from the meeting via a web questionnaire and were asked again to disclose any potential conflict of interest.

The Consensus Conference decided not to address echocardiography and the drugs/techniques/strategies already addressed in the guidelines for the management of Sepsis and ARDS, and for peri-operative blood conservation and transfusions.

## RESULTS

Three-hundred-forty participants from 65 countries (*Figure 1 and Figure 2*) suggested 120 topics: 17 of them were supported by an article with a significant effect on mortality (2-20) while 103 topics were not (*Figure 3*).

Ten drugs/techniques/strategies were considered to have evidence strong enough to

**Table 2** - Seven drugs/techniques/strategies had at least one study showing a statistically significant difference in support of their effect on mortality. Despite this the Consensus Conference decided not to include them among the most important topics for the reasons provided below. In addition we have reported the percentage of participants that proposed the intervention as having an effect on mortality during the first web-vote.

Alpha 2 adrenergic agonists (45 %)	A meta-analysis of RCTs <sup>13</sup> suggested a reduction in perioperative all cause mortality in patients receiving alfa-2 adrenergic agonists (clonidine, dexmedetomidine, or mivazerol). The Consensus Conference decided not to include this intervention as the majority of this evidence comes from patients undergoing vascular surgery and not from a cardiac surgery specific setting.
Epidural analgesia (38 %)	A meta-analysis of RCTs <sup>13</sup> suggested a reduction in the composite endpoint of mortality (longest follow up available, up to 13 years) and/or myocardial infarction in patients receiving perioperative epidural analgesia. The Consensus Conference decided not to include this technique due to safety issues (underreporting of rare complications) and the use of a composite end-point to achieve statistical significance.
Fenoldopam (34 %)	Two meta-analyses of RCTs <sup>14, 15</sup> suggested that fenoldopam can reduce all cause in hospital mortality in patients with or at risk for acute renal failure. The Consensus Conference decided that the evidence comes from critically ill patients <sup>14</sup> and from cardiovascular patients <sup>15</sup> and not from a cardiac surgery specific setting.
Nesiritide (24 %)	A single underpowered RCT <sup>16</sup> suggested a reduction in 180-day mortality in cardiac surgery with the use of nesiritide, but a recent meta-analysis did not confirm this finding <sup>17</sup> .
Norepinephrine vs dopamine (48 %)	A recent RCT <sup>18</sup> suggested a 28-day mortality reduction in patients with cardiogenic shock when compared to dopamine. The Consensus Conference decided that the evidence comes from patients with cardiogenic shock and not from a cardiac surgery specific setting. Furthermore, the dosage of dopamine reported in the study was much higher than generally used.
Off-pump coronary artery bypass grafting (11 %)	A recent meta-analysis of RCTs <sup>19</sup> suggested an increase in long term mortality in patients operated with the off-pump techniques. The Consensus Conference decided that, since this was a specific surgical decision, this topic was not among the core topics of the Consensus Conference. Furthermore, this article <sup>19</sup> focused on late ( $\geq 1$ year mortality).
Pexelizumab (32 %)	A subgroup analysis of a meta-analysis of RCTs <sup>20</sup> suggested that pexelizumab might reduce mortality (longest follow up available, up to 6 months) in patients undergoing CABG. This topic was not included among the most important topics as it was the only topic that did not receive a sufficient percentage of votes from the audience (32 % at the first round and 35 % at the second round).

support their effect on mortality and are listed in table 1 together with a consensus statement.

The level of agreement of participants before and after the meeting of Milan on June 28<sup>th</sup> is detailed in table 1 and 2 with 214 and 150 participants voting at the first and second round respectively.

Declared conflict of interests ranged from

2 % (IABP, statins) to 6 % (levosimendan, volatile agents) without affecting results and percentages of agreement.

Seven topics with an article supporting their effect on mortality were not included among the final topics and are listed in table 2 with the reasons for their exclusion.

The suggested topics without at least one



**Figure 1**  
*The 65 countries that participated in the consensus conference.*

peer reviewed published article to support their effect on mortality were either eliminated (if not deemed of potential value) or grouped and summarized as minor topics in table 3 (if considered of potential value).

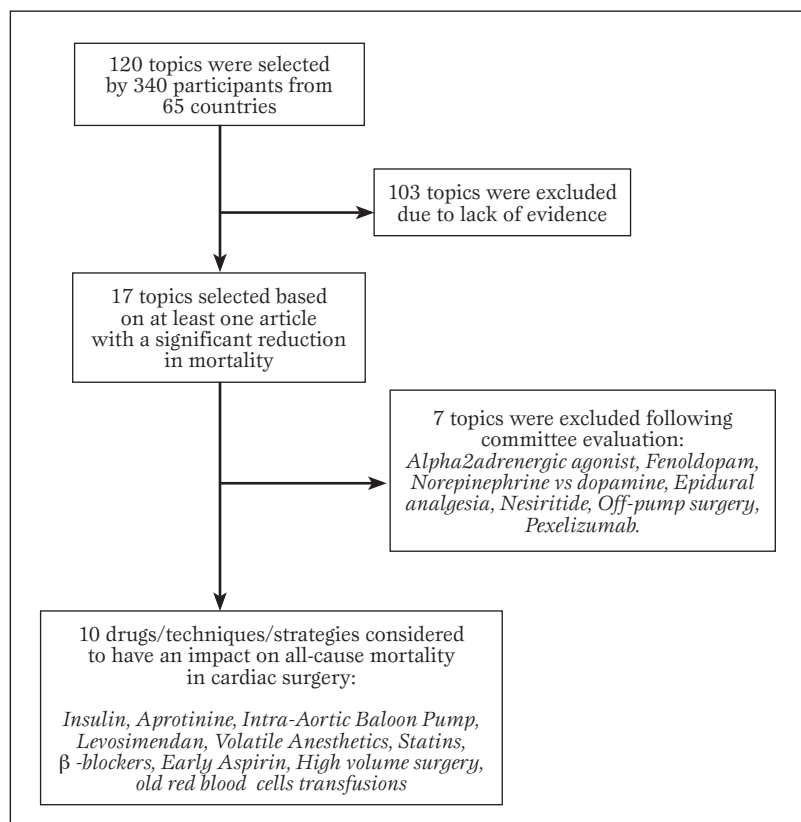
The Consensus Conference stated that these minor topics might be beneficial/detrimental in terms of survival in the perioperative setting, but acknowledged that there is still no evidence base to support them.

## DISCUSSION

This is the first consensus statement of its kind examining non-surgical interventions aimed at reducing mortality in cardiac surgery. It was hoped that its creation would provide a starting point for researchers and donors as well as serve as a guide for clinicians. The findings contained in this document provide then, for the first time, a comprehensive review of these non-surgical interventions.



**Figure 2**  
*Most European countries participated in the consensus conference*

**Figure 3**

*Flow chart on the selection of major topics (from the 120 suggested topics to the identification of the topics with a statistically significant effect on perioperative mortality in cardiac surgery).*

The majority of the interventions described as potentially having an impact on mortality (*Table 1*) are cheap and simple to perform which hold the promise that their worldwide adoption or in some cases avoidance, could have a significant impact on cardiac mortality worldwide. To realise the potential life saving effects of these interventions it is imperative that steps be taken to validate these findings. This should be in the form of an RCT large enough to detect a reduction in mortality. It is sobering to realise that no randomized clinical trial of more than 10,000 patients has ever been conducted in the field of perioperative cardiac surgery.

It is reasonable to assume that these findings may, at least in part, be applicable to non-cardiac surgery and general intensive care settings. As these populations are

much larger their use may result in even greater mortality reductions.

The Consensus Conference identified seven other interventions with a potential effect on mortality (*Table 2*).

These were excluded for a wide range of reasons ranging from concerns regarding study endpoints to the exclusion of studies conducted in populations other than cardiac surgery. Their exclusion does not reflect a rejection of the intervention in its entirety and there is value in further investigating these interventions.

Systematic reviews with meta-analysis have become popular in the anesthesia and surgical literature and currently dominate the evidence based hierarchy (21).

They have a high impact on healthcare decision makers, clinicians, and patients alike and are a guide to decision making

**Table 3 - Minor topics (without a statistically significant study to support their effect on mortality).**

<b>Panel A</b> Minor topics evaluated by the consensus conference and deemed of potential value in reducing mortality in cardiac anesthesia and intensive care despite a current lack of evidence to support this evaluation.	
<b>Risk stratification</b>	Pre and postoperative risk scores
	Preoperative evaluation
	Pre and postoperative cardiac biomarkers (including brain natriuretic peptide and troponins before and after cardiac surgery)
<b>Real time monitoring</b>	Epiaortic scan
	Pulmonary artery catheter
	Tissue perfusion monitoring (intra and post-operative, including SvO <sub>2</sub> , lactates and the best perfusion pressure)
	Near-infrared spectroscopy (NIRS)
<b>Drugs</b>	Steroids
	Calcium Antagonists
	Enoximone
<b>Cardiopulmonary bypass (CPB)</b>	Best hematocrit during CPB
	Cardioplegic solution
	Ultrafiltration
	Intraaortic balloon pump to induce pulsatile flow during CPB
	Pulsatile flow CPB
	Volatile agent administration during CPB
	Mini CPB
<b>Perioperative management</b>	Remote ischemic preconditioning
	Management of perioperative body temperature, including therapeutic hypothermia after cardiac arrest and in low cardiac output syndrome
	Prevention of bleeding and transfusion (including tranexamic acid, thromboelastography and management of preoperative anemia)
	Non invasive ventilation (early after extubation)
	Fast track
	Extracorporeal Membrane Oxygenation (ECMO)
	Management and treatment of acute kidney injury including early renal replacement therapy, bicarbonates and the use of early renal injury biomarkers
	Prevention and treatment of delirium and cognitive dysfunction
	Post-op pain management
	Early enteral nutrition
<b>Minimally invasive surgical techniques</b>	Transcatheter aortic valve implantation
	Percutaneous mitral valve repair
	Minimally invasive surgical techniques
<b>Training</b>	
<b>Panel B</b> Minor topics evaluated by the consensus conference and deemed of uncertain value in reducing mortality in cardiac anesthesia and intensive care despite a current lack of evidence to support this evaluation.	
Ace inhibitors	
Positive end expiratory pressure	
Recombinant activated Factor VII	
Preoperative management of antiplatelet drugs, especially in patients with stents	
<b>Panel C</b> Minor topics evaluated by the consensus conference and deemed to increase mortality in cardiac anesthesia and intensive care despite a current lack of evidence to support this evaluation.	
Cox2 inhibitors	
Furosemide in acute kidney injury	
Transfusion of blood products	



with a similar clarity to that of randomized trials. To gain maximal benefit from systematic reviews it would be beneficial if researchers adopt a standardised manner of randomized study reporting.

This would significantly improve the ability to compare various studies with each other. Furthermore, researchers, reviewers and editorial boards of peer reviewed journal should understand the importance of reporting clinically relevant outcomes with the intention to treat analysis even when publishing small RCTs focusing on surrogate endpoints.

The manner in which this conference has been conducted is a reflection of how use can be made of current electronic resources to maximise participation and more importantly to ensure that all relevant clinical information is identified and evaluated.

With the ever increasing proliferation of clinical evidence this consensus conference may serve as a model on how to synthesis and disseminate clinically relevant information.

In a field such as cardiac surgery where patients are still faced with a high risk of perioperative morbidity and mortality it is imperative to foster the dissemination of results that may impact on patient outcome.

It is interesting to note that the two interventions that received the highest percentage of support (beta-blockers - 94 % and the use of early aspirin - 87%) received this support without there being any RCTs or meta-analysis of RCTs regarding their use in cardiac surgery.

This suggests that clinicians and scientists are not fully aware or do not completely agree with the evidence based hierarchy. It may in addition reflect a tendency to extrapolate findings from one aspect of medicine and apply it to another without consideration to the levels of support for these actions.

Finally all 17 of the papers described in table 1 and 2 were published in the last decade, suggesting that scientific awareness and investigation into this field is rapidly increasing.

*Limitations of the present work* - In general there is a dearth of evidence based medicine in this sector of cardiac surgery. Only two out of ten major papers described large RCTs, and three papers were meta-analysis of small RCTs.

The other five papers were either non-RCTs or meta-analysis including non-RCTs, testifying the paucity of large RCTs in this specific setting.

## CONCLUSIONS

By conducting a comprehensive updated International Consensus Congress we have identified all the ten ancillary drugs/techniques/strategies that might reduce mortality in cardiac surgery.

We thus suggest that future research and funding be directed toward these topics.

### *Endorsements*

The Consensus Conference was endorsed by the Italian Ministry of Health, the Italian Association of Cardiothoracic Anesthesiologists (ITACTA), the Italian Society for Cardiac Surgery (SICCH), the Meta-analysis and Evidence-based Medicine Training in Cardiology (METCARDIO), EXPO Milano 2015, the SIAARTI (Società Italiana Analgesia Anestesia Rianimazione Terapia Intensiva) study group of cardiothoracic and vascular anesthesia, the Colombian Cardiovascular Committee of the Colombian Anesthesia Society, and the Italian Critical Care Nurses Association (AISACE).

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You're welcome to participate to the "first international consensus conference on mortality reduction in anesthesia" that will take place in Milan, Italy, in June 2011.  
Please send an email to [landoni.giovanni@hsr.it](mailto:landoni.giovanni@hsr.it) to suggest topics or to offer participation or endorsement to the event.

**Cite this article as:** Landoni G, Augoustides JG, Guarracino F, Santini F, Ponschab M, Pasero D, Rodseth RN, Biondi-Zoccai G, Silvay G, Salvi L, Camporesi E, Comis M, Conte M, Bevilacqua S, Cabrini L, Cariello C, Caramelli F, De Santis V, Del Sarto P, Dini D, Forti A, Galdieri N, Giordano G, Gottin L, Greco M, Maglioni E, Mantovani L, Manzato A, Meli M, Paternoster G, Pittarello D, Rana NK, Ruggeri L, Salandin V, Sangalli F, Zambon M, Zucchetti M, Bignami E, Alfieri O, Zangrillo A. Mortality reduction in cardiac anesthesia and intensive care: results of the first International Consensus Conference. HSR Proceedings in Intensive Care and Cardiovascular Anesthesia 2011; 3 (1): 9-19

**Source of Support:** The consensus conference was supported by departmental funds only. Dr R.N. Rodseth is supported by a CIHR Scholarship (the Canada-HOPE Scholarship), **Conflict of interest:** Landoni G. received speaker fees from: Abbott, Baxter, Minrad, Cephalon, Orion. Caramelli F. received speaker fees from Cephalon. **Acknowledgements:** Participants from the following 65 countries, listed in alphabetical order, contributed to the conference: Albania, Argentina, Australia, Austria, Azerbaijan, Bahrain, Bangladesh, Belgium, Brazil, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, Ecuador, Egypt, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, India, Iran, Iraq, Italy, Japan, Jordania, Kenya, Libya, Lithuania, Malaysia, Mexico, Myanmar, Nederland's, Nepal, New Zealand, Nigeria, Norway, Panama, Peru, Poland, Romania, Russia, Saudi Arabia, Slovak Republic, South Africa, Spain, Sudan, Sweden, Switzerland, Taiwan, Tunisia, Turkey, Turks and Caicos, Uruguay, UK, Ukraine, USA, Venezuela, Yemen.