

## **A modified Delphi process to determine surgical COVID-19 research priorities: PRODUCE study**

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### **Endorsing Societies:**

Association of Surgeons of Great Britain and Ireland (**ASGBI**)  
Association of Upper Gastrointestinal Surgery of Great Britain and Ireland (**AUGIS**)  
Indian Association of Gastrointestinal Endosurgeons (**IAGES**)  
Society of American Gastrointestinal and Endoscopic Surgeons (**SAGES**)  
World Society of Emergency Surgery (**WSES**)

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## **A modified Delphi process to determine surgical COVID-19 research priorities: PRODUCE study**

Abstract:

### **Background:**

The current COVID-19 global pandemic caused major disruption to surgical services and acute surgical care worldwide emphasizing the need for international collaboration to determine the most pressing COVID-19 related surgical research priorities. The aim of this study was to use a modified Delphi process to determine these, to ensure high-quality research in the future.

### **Method:**

Surgical stakeholders (multidisciplinary healthcare professionals and patients) were invited by email using surgical society membership details or Twitter to submit individual research questions via an online survey (phase I). Two rounds of prioritisation by stakeholders (phase II and III) were then completed to determine a final list of research questions. All questions were analysed on an anonymised basis.

### **Results:**

A total of 510 questions were submitted by 130 stakeholders in phase I, 96 of which were taken forward for prioritisation in phase II, completed by 213 stakeholders. Following Phase II analysis, 216 stakeholders prioritised 39 questions in Phase III, resulting in a final list of 13 focused questions. Stakeholders were predominantly general surgeons but included clinical-scientists and patients from over 50 countries.

**Conclusion:** The study has identified 13 key research priorities relating to surgery during the COVID-19 pandemic. Funding applications, to establish well-designed, high-quality international collaborative research outcomes are now required to address these questions as a matter of urgency.

## **Introduction**

. As healthcare systems around the world prepared to cope with the pandemic, surgical services made significant adjustments to what would be considered standard of care. These changes included expanding critical care facilities by turning surgical theatres into additional ICUs, postponing non-urgent, non-cancer surgical procedures, and the redeployment of surgical staff to support other medical specialties. The rapid spread of infection and the need for a swift response demanded immediate decisions regarding all phases of care. Unfortunately these critical decisions were made in the absence of data to help guide the processes and conclusions. A systematic review of all literature relating to surgery and COVID-19 included just 11 publications (9 expert opinions and 2 observational studies). All publications originated from either China or Japan, despite COVID-19 being present in at least 156 countries at the time of publication (1). There has never been a greater requirement for more research to inform surgical practice. At the same time, there are no data on what the stakeholders would regard as the most important research questions when it comes to surgery. We, therefore, felt that there was a need for urgent international collaboration to determine the most pressing COVID-19 related surgical research priorities.

A modified Delphi process provides a methodological and collaborative system to develop a list of research priorities by consensus from a group of experts. This approach has been found to improve efficiency, reduce bias, and enhance future research impact. It has previously been shown to be successful in colorectal (2), orthopaedic (3), plastic (4), bariatric (5), and benign upper-gastrointestinal surgery (6). The aim of our study was to use a modified Delphi process to identify a highly prioritised and consensus agreed list of surgical COVID-19 research priorities.

## **Methods**

A modified Delphi process was undertaken in three phases (Fig. 1). This process included two distinct rounds of prioritisation and utilised established methodology previously described for a number of similar exercises (7, 8). Stakeholders were asked to submit questions and, thereafter, prioritise their responses based on surgical relevance and answerability. There is no clear consensus on cut-off points for Delphi studies (9). To encourage maximal participation, no stipulations were made to require contributors to complete all phases of the study. All contributors were treated equally. It was accepted that there would likely be significant variation in the numbers of contributors between phases. Formal ethical approval was not required for this study, as confirmed by the decision-making tool on the online National Research Ethics Service (10).

Stakeholders were invited to participate from around the world from backgrounds including medical professionals, patients, and members of the wider multidisciplinary team such as clinical scientists and specialist nurses. We included patient representation on our steering committee. The study was endorsed by the Association of Surgeons of Great Britain and Ireland (**ASGBI**); Association of Upper Gastrointestinal Surgery of Great Britain and Ireland (**AUGIS**); Indian Association of Gastrointestinal Endosurgeons (**IAGES**); Society of American Gastrointestinal and Endoscopic Surgeons (**SAGES**); and World Society of Emergency Surgery (**WSES**).

### **Steering committee**

The COVID\_PRODUCED steering committee consisted of one surgical trainee (MA), 18 consultant/attending surgeons (AP, BZ, FC, GT, HA, JM, KM, MC, MT, MW, NS, RG, RP, SK, SM, and SW,) one clinical researcher (YG), and lay representation (LL, ND, SB). The role of the steering committee was to ensure the relevance of the submitted questions from both a clinical and patient perspective and to provide consensus agreement. MA, KM, and MW led on the design and conduct of the study. The remaining members of the steering committee contributed to assessing the validity of questions, agreed on amendments to questions, and the cut-off points between phases. All members of the steering committee have made significant contributions to the final manuscript and have agreed on the findings.

## **Phase I**

The social media platform Twitter was used to invite questions from stakeholders. This solicitation was principally achieved by using a dedicated study Twitter account (@COVID\_PRODUCED) and also by the use of retweets through the study endorsing surgical society accounts. Members of endorsing societies were also made aware of the study through society emails. Stakeholders were invited to submit research questions across the entire spectrum of "Surgery in the COVID-19 pandemic" via an online survey (<https://surveyMonkey.com>). There was no limit on the number of questions that an individual could submit. The survey was open for a total of 31 days (8th April-2nd May 2020), with 5 tweet reminders and 68 re-tweets during this period.

At the end of Phase 1, questions were collated, reviewed by the steering committee and categorized as follows: (1) General; (2) Emergency; (3) Elective; (4) Theatre Environment and Technical Consideration; (5) Training; (6) Laparoscopy; (7) Protective Equipment; (8) Cancer Surgery. Duplicate questions and questions not related primarily to surgical practice were removed. Questions with a similar theme were amended and combined by agreement of the steering committee. Care was taken not to alter the meaning of the submitted questions and disagreements were resolved by consensus.

## **Phase II**

Stakeholders were asked to prioritise the questions from Phase 1 using a Likert Scale (1 – lowest research priority to 5 – highest research priority) using SurveyMonkey. Social media and society emails were again used to highlight the prioritisation process amongst stakeholders. The survey remained open to submissions for 72 hours. The question order was randomly assigned to each stakeholder, thereby attempting to reduce bias if the survey was not 100% completed prior to submission. Results were reviewed by the steering committee, who were blinded to the questions by assigning a code to individual questions. Each code was then scored using a weighted mean with an agreed 'cut-off'  $\geq 3.8$  for inclusion in phase III. The cut-off was agreed upon by the committee after a detailed discussion.

## **Phase III**

Stakeholders performed a final round of prioritization using a 5-point Likert Scale. The survey remained open for 72 hours and the question order was again randomly assigned. Results were reviewed by the steering committee who were blinded to the questions in the same manner as phase II, to identify the final list of prioritised questions. The criteria for inclusion in the final list of research priorities was a mean score of  $\geq 4.0$ , a score of 1 or 2 by  $<10\%$ , and 4 or 5 by  $>70\%$  of stakeholders. All three criteria had to be met to be included in the final list of research priorities.

## **Results:**

A total of 510 research questions were submitted by 130 stakeholders during Phase I (Fig 2). Stakeholders submitted a median number of 4 questions (range 1-10). Questions were submitted from predominantly general surgeons but included clinical scientists, patients, and other medical specialties (Table 1) from 25 countries (Fig 3a). Following review by the steering committee, 96 questions were moved forward for prioritisation in phase II.

Two-hundred and thirteen stakeholders prioritised the questions in phase II, with a 90.6% completion rate from 34 countries (Fig 3b) and predominantly general surgeons (Table 1). A total of 39 questions met the criteria for inclusion in phase III.

Thirty-nine questions were prioritized by 216 stakeholders from 26 countries, with a 90.3% completion rate in phase III (Table 1 & Fig 3c). At the end of phase III, 13 questions met the criteria to be defined as a high research priority (Table 2).

Included in the final list were questions from 5 categories: General (n=5); Theatre environment and technical consideration (n=4); Laparoscopy (n=2); Protective equipment (n=1); Elective Surgery (n=1). The questions (n=26) which failed to make the final list of research priorities from phase III are shown in Appendix 1. Thirty-eight stakeholders participated in at least two of the three phases throughout the Delphi process.

## **Discussion:**

The COVID-19 pandemic has had a significant impact on global surgical activity which will persist for an unknown period of time (11). There are suggestions that this virus may not ever completely disappear and that for the foreseeable future the surgical community will have to learn to live with it. It is, therefore, crucial that we develop an evidence base quickly to guide clinical decision making in a radically changed environment. To the best of our knowledge, this is the first attempt at identifying key surgical research priorities in COVID-19 times.

Our 3-stage modified Delphi process has yielded a list of 13 high priority surgically focused COVID-19 research questions. This was achieved by utilizing the collective expertise and views of multiple surgical stakeholders. This work was undertaken as a matter of urgency and was completed within 31 days due to the significant impact that the COVID-19 pandemic has had on the global population and surgical practice. Remarkably, this work involved stakeholders from 52 countries, encompassing all 6 continents. The study was further supported by five reputed surgical societies worldwide. The true extent of the potential impact on surgical care is yet to be fully defined.

Many of the 13 final questions focus on the aerosolization of virus particles in the theatre/procedural environment (Theatre environment and technical consideration, n=3; Laparoscopy, n=1; General, n=1) and surgical outcomes associated with SARS-CoV-2 infection (General n=3). These findings are not unexpected. It is evident that there is significant uncertainty regarding the intraoperative risk of SARS-CoV-2 transmission to members of the operating team and the highly publicised variability in the availability of personal protective equipment supplied throughout the world. Emergent surgical intervention for the most common pathologies (e.g gastrointestinal perforation, acute appendicitis, trauma) will still be necessary during the pandemic. A safe strategy to facilitate emergency surgery, supported by best evidence is fundamental to both the safety of the patient and healthcare staff. Interestingly, our findings share some commonality to a recent study of COVID-19 operating room best practice (12).

Also, there is great debate globally about which time-dependent, non-emergency procedures should be undertaken (e.g. oncological resection, transplant). The risk of delaying the procedure versus the risk of morbidity from SARS-CoV-2 infection is an unknown entity that needs to be prioritized, as is



the question of which patients are more susceptible, due to their morbidities. It is therefore surprising that this topic failed to achieve the required cut-off for inclusion in our final list of priorities, and yet remains such a significant topic of debate. Nevertheless, a recent publication has made attempts to address this issue with the proposal of a scoring system to facilitate the selection of patients for 'medically necessary, time-sensitive procedures' (13).

We chose to use the social media platform Twitter as the primary avenue to disseminate awareness and invite participation in our study. Previous analysis of the use of Twitter accounts to increase initiation and ongoing engagement of stakeholders and the public during international and national studies has proved to be very successful (14). This is particularly the case when there is additional tagging of institutions and societies and integration of images, as was the case in our study. In our study, 11 tweets were sent out to the public from the dedicated twitter account: Phase I (n=6); Phase II (n=3); Phase III (n=3). The mean number of impressions achieved by a tweet in each phase was as follows; Phase I - 4633; Phase II - 2022; Phase III - 6778. The number of stakeholders who took part in each phase of the study steadily increased (130 in phase I, 213 in phase II and 216 in phase III). It is unusual for participation in Delphi phases to increase between each phase. This may reflect an increasing awareness of the effects of COVID-19 in the surgical community as it spread globally, or perhaps word of mouth given the speed with which the study was undertaken. However, consistent participation across the phases from stakeholders was low. 38 stakeholders took part in at least two phases, and the reasons for this low level of consistent engagement are not immediately apparent.

There are limitations to our study. Understandably, countries with the highest response rate were those nations in which surgical societies supported the study (SAGES, ASGBI, IAGES, AUGIS, and WSES). The majority of stakeholders were from developed countries, where research priorities may be substantially different to those in developing countries. In addition, lower response rates were noted from certain countries where the virus first emerged. This result might be due to the substantial barrier to certain social media platforms such as Twitter by countries such as China, the original epicenter of the virus. However, it would have been beneficial to have greater representation from these countries given their considerable experience and length of time they have been tackling COVID-19. Certainly, publications relating to surgery and the COVID-19 pandemic have originated predominantly from China and Singapore, including 9 expert opinion and 2 observational studies (15-

25)(11-21). Interestingly, 8 of these papers specifically mentioned measures, such as chest CTs and regular viral swabbing of healthcare professionals involved in the care of surgical patients. This mimics the common theme in many of the final questions our study generated looking at which procedures were aerosol-generating and appropriate methods to best protect staff.

The authors recognise that within each category a number of the 13 questions have some repetition. Our findings reflect the views of our global stakeholders and we made efforts to ensure transparency between phases and that stakeholders all had an equal voice. Nevertheless, one could suggest that further research could be condensed down to five key areas based on these 13 questions:

aerosolization of SARS-Cov-2 particles during surgical procedures; effective PPE to be used during surgery; pre-operative screening prior to surgery; does the presence of antibodies confer immunity; SARS-CoV-2 infection and surgical outcomes. The authors also acknowledge that ongoing studies may specifically address some of our prioritised questions (26). Certainly the question of surgical outcomes following infection is already being addressed by the CovidSurg studies, which has recruited over 12000 patients thus far. This Delphi study can therefore only act to validate the need for the CovidSurg and CovidSurg-Cancer studies (11).

In an ideal setting, the authors acknowledge that we lack significant patient involvement. We made efforts to include lay representation, but due to time constraints and the desire to determine the most pressing surgical research priorities we opted not to focus on this aspect of the study. It should also be acknowledged that engaging with patients in the traditional face to face environment to gather their views in the current environment would not have been serving the best interests of our patients.

All Phase III questions (Appendix 1) have been published in this document to acknowledge that a proportion of these questions are linked by category or topic. It is hoped that our list of surgical research priorities will enable the international surgical community to focus their research efforts and validate those that are already ongoing.

In conclusion, in the midst of COVID-19 pandemic, we have undertaken a rapid modified Delphi consensus-building process to produce a list of surgical COVID-19 research priorities. The global surgical multidisciplinary teams are asked to take note, galvanise and work together in a collaborative

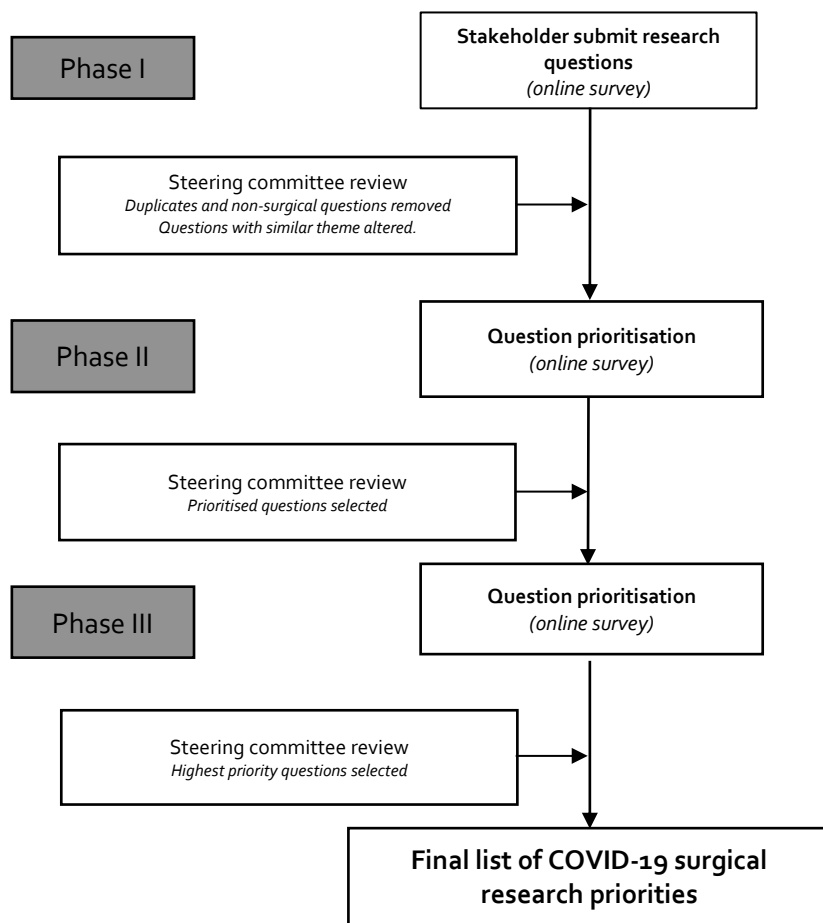
setting to address these research questions in the interest of delivering optimal care for our patients in these very challenging times.

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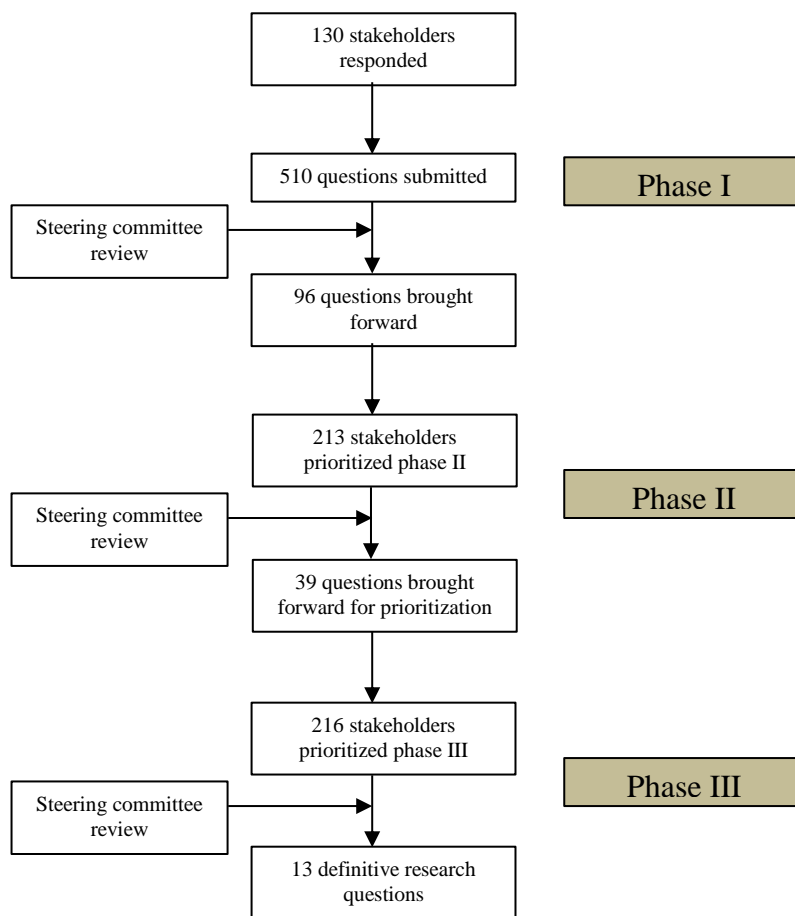
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**Fig 1. Three phase modified Delphi methodology**



**Fig 2 – Overview of responses for modified Delphi Survey**



**Table 1 – Category of stakeholders in Phase I, II and III**

<b>Specialty</b>	<b>Number of stakeholders</b>		
	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III</b>
<b>General Surgeon</b>	124	197	200
<b>Clinical Scientist</b>	2	6	7
<b>Medical Physician</b>	2	2	1
<b>Patient</b>	1	1	1
<b>Surgeon (other)*</b>	1	3	5
<b>Nurse</b>	-	1	-
<b>Junior Doctor/ Medical Student</b>	-	3	1
<b>Dentist</b>	-	-	1

\*Surgeons (other): Trauma and Orthopaedics, Paediatric, Plastic, Urology, Obstetrics and gynaecology

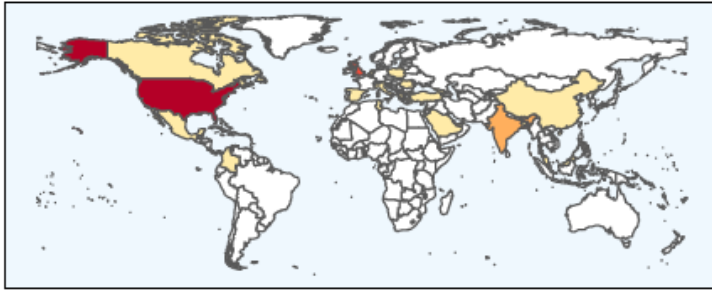


Table 2 – Final list of prioritized research questions

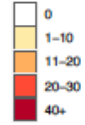
<u>Category</u>	<u>Questions</u>
<b>Theatre environment and technical consideration</b>	Are SARS-CoV-2 particles aerosolized during endoscopy, laparoscopy or open surgery?
<b>Theatre environment and technical consideration</b>	What are the most effective methods for preventing the spread of SARS-CoV-2 during aerosol generating procedures?
<b>Theatre environment and technical consideration</b>	What are the risks of SARS-CoV-2 aerosol generation in the use of electrocautery devices during the COVID-19 pandemic?
<b>Theatre environment and technical consideration</b>	What are the safest approaches to protect the theatre team from COVID-19 transmission during open and laparoscopic surgery?
<b>Laparoscopy</b>	Is laparoscopy an aerosol generating procedure, and if so what precautions should be taken before, during and after laparoscopic surgery?
<b>Laparoscopy</b>	What is the risk of SARS-CoV-2 virus transmission during laparoscopic/MIS surgery?
<b>Protective Equipment</b>	What personal protective equipment should be donned by the operating team undertaking a surgical procedure (open, laparoscopic or robotic) during the COVID-19 pandemic?
<b>Elective Surgery</b>	Should all patients undergoing elective surgical procedures be tested for COVID-19 prior to surgery and how should they be screened?
<b>General</b>	Are COVID-19 positive patients at risk of transmitting the SARS-CoV-2 virus to the healthcare team through bodily fluids or aerosolized particles?
<b>General</b>	Does the presence of SARS-CoV-2 antibodies confer protection from reinfection?
<b>General</b>	Is there an increased incidence of perioperative complications in COVID-19 positive patients following surgery (e.g. SSI, VTE/PE)?
<b>General</b>	What are the principal factors influencing mortality in COVID-19 surgical patients?
<b>General</b>	What is the impact of COVID-19 infection on surgical outcomes?

**Map showing stateholders' geographical pattern in different phases**

A.

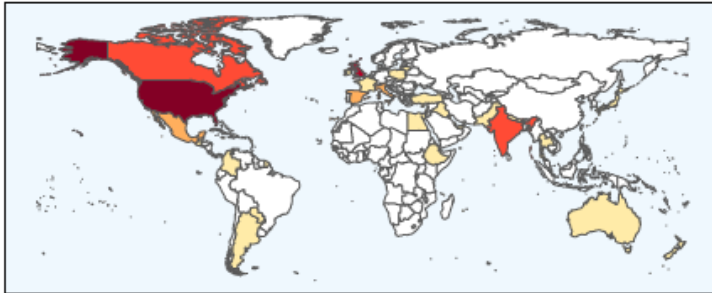


Responses

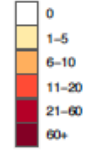


Continents	Number of stakeholders
Africa	1
Asia	24
Australasia	-
Europe	49
North America	55
South America	1

B.

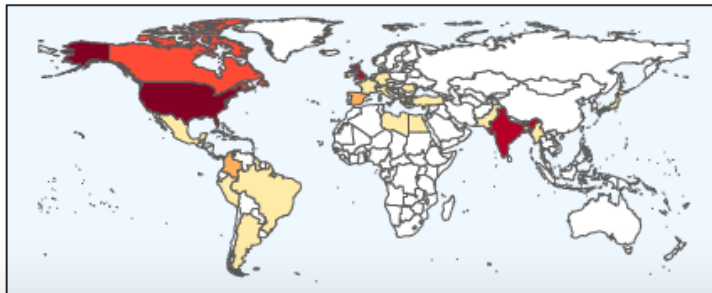


Responses

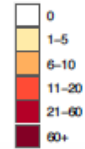


Continents	Number of stakeholders
Africa	1
Asia	31
Australasia	2
Europe	65
North America	108
South America	6

C.



Responses



Continents	Number of stakeholders
Africa	1
Asia	37
Australasia	-
Europe	64
North America	101
South America	13