European Spine Journal (2018) 27 (Suppl 6):S879–S888
https://doi.org/10.1007/s00586-017-5332-z

ORIGINAL ARTICLE

The Global Spine Care Initiative: a consensus process to develop and validate a stratification scheme for surgical care of spinal disorders as a guide for improved resource utilization in low- and middle-income communities

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Received: 10 July 2017 / Revised: 19 September 2017 / Accepted: 4 October 2017 / Published online: 16 October 2017

Abstract

Purpose The purpose of this study was to develop a stratification scheme for surgical spinal care to serve as a framework for referrals and distribution of patients with spinal disorders.

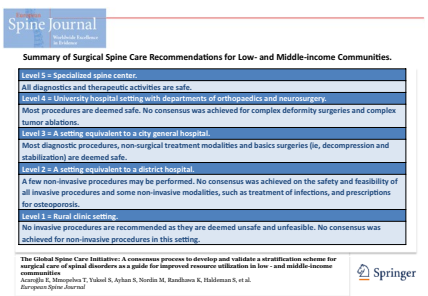
Methods We used a modified Delphi process. A literature search identified experts for the consensus panel and the panel was expanded by inviting spine surgeons known to be global opinion leaders. After creating a seed document of five hierarchical levels of surgical care, a four-step modified Delphi process (question validation, collection of factors, evaluation of factors, re-evaluation of factors) was performed.

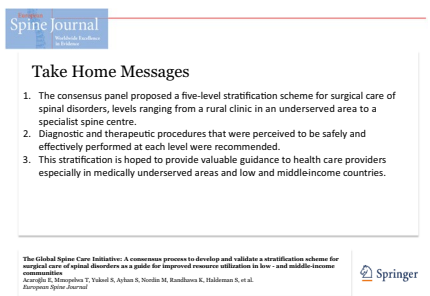
Results Of 78 invited experts, 19 participated in round 1, and of the 19, 14 participated in 2, and 12 in 3 and 4. Consensus was fairly heterogeneous for levels of care 2–4 (moderate resources). Only simple assessment methods based on the clinical skills of the medical personnel were considered feasible and safe in low-resource settings. Diagnosis, staging, and treatment were deemed feasible and safe in a specialized spine center. Accurate diagnostic workup was deemed feasible and safe for lower levels of care complexity (from level 3 upwards) compared to non-invasive procedures (level 4) and the full range of invasive procedures (level 5).

Conclusion This study introduces a five-level stratification scheme for the surgical care of spinal disorders. This stratification may provide input into the Global Spine Care Initiative care pathway that will be applied in medically underserved areas and low- and middle-income countries.

Graphical Abstract

These slides can be retrieved under Electronic Supplementary Material.





Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00586-017-5332-z) contains supplementary material, which is available to authorized users.

Extended author information available on the last page of the article

Keywords Spine · General surgery · Surgical procedures · Operative · Delivery of health care · Health care facilities, manpower, and services

Introduction

Spinal disorders are a heterogeneous group of specific and non-specific musculoskeletal diseases involving the spinal column. Although not recognized as a major cause of disease burden until recently, there has been a paradigm change over recent decades and the burden of disease globally has shifted substantially from communicable, maternal, neonatal, and nutritional disorders towards non-communicable diseases, especially diseases associated with pain and disability, led by spinal disorders [1].

The World Health Organization (WHO) estimates that the prevalence of spinal disorders in developed countries is as high as 85% [2]. Low back pain (LBP) and neck pain are the leading global cause of years lived with disability (YLDs) and fourth leading cause of disability adjusted life-years (DALYs) after ischaemic heart disease, cerebrovascular diseases, and lower respiratory infection [3, 4].

One major factor that has increased the importance of spinal disorders in the hierarchy of problems to be prioritized over the last decades is the global increase of burden of spinal disorders not only in high-income countries but also in low- and middle-income communities [3, 4]. In a systematic review by Louw et al., the 1 year prevalence of LBP among Africans ranged from 14 to 72%, which is comparable to that of the developed countries [5]. The prevalence of cervical spondylosis in Africa is comparable to that of industrialized countries [6]. Furthermore, Sub-Saharan Africa has additional unique socio-economic challenges including high HIV infection rates, increasing adoption of the western-diet leading to an increasing obesity problem and type II diabetes, poor overall nutrition (qualitatively as well as quantitatively), resource challenges and high illiteracy rate. These challenges mandate a management approach that is tailored to the socio-economic and cultural dynamics of this region and yet maintaining sustainability.

The shift of burden of diseases globally from communicable to non-communicable diseases needs to be reflected by change in health system investments and education reform [1, 7]. Spinal disorders such as back pain may not be managed effectively in Africa and other medically underserved areas and low- and middle-income countries. In most parts, treatment methods applied do not conform to international evidence-based practice [8]. Most international practice guidelines are not recognized in underserved populations due to possible issues such as cultural context and resources needed to implement. For example, Botswana (home country of author, TM), a country with a population of around two million people has only one medical center where spine procedures can be safely performed. In addition to the shortage of centers, there exists an even more important shortage of trained personnel due to which most spinal care has to be given by general practitioners and/or other medical personnel including physical therapists, chiropractors, nurses, midwives, traditional healers and others. All of these clinicians handle patient consultations, clinical assessments, prescriptions and referrals. The lack of a support system or implementation and evaluation of evidence-based clinical guidelines inadvertently leads to delayed referral, missed pathologies and inappropriate treatments. This statistic is probably applicable to most areas in Sub-Saharan Africa as well as several areas with large populations throughout the world, even in some regions within seemingly over-served countries.

The present study originated from the perception that outlining recommendations for the stratification of surgical spinal care, to create a framework of "what can safely be done where" to improve quality of care. Such recommendations need to start with items of clinically triaging the patient seeking care at the time of presentation to "what can safely be done in different clinical scenarios". Primary health care providers must be informed on "what constitutes a case for spine surgery and which cases do I need to refer for surgical treatment". Lastly, if a patient needs surgical care, "where can it be given in a safe manner?"

Therefore, the aims of this study were to develop and validate a stratification scheme of surgical spinal care to serve as a framework for surgical referrals and distribution of patients with spinal disorders in medically underserved areas and low- and middle-income countries that may inform the Global Spine Care Initiative care pathway.

Methods

A modified Delphi process was selected based on the understanding that developing recommendations for surgical care for spinal disorders would require a knowledgeable panel from various geographical locations who are not only expert spine surgeons but also have experience in delivering health care for spinal disorders in a wide array of environments and with variable levels of resources. The Delphi process is a widely used and accepted method for gathering data and achieving convergence of expert opinions in different parts of the world within their domain of expertise [9]. The Delphi process has been used in various fields of studies such as policy development and resource utilization to establish a full range of options. The main advantage of using the

Delphi technique is the ability to provide anonymity and confidentiality to panel members in terms of their responses [8, 10, 11], and avoiding group dynamics such as manipulation or coercion [12, 13]. Controlled feedback in the Delphi process is designed to reduce the noise effect within a group process and focusing on problem solving, therefore, eliminating bias [14]. We maintained confidentiality and anonymity of all participants during the process aiming to avoid inter-expert interactions.

Identification of the expert panel

Computerized bibliographic databases were searched from 1960 to 2015. Databases searched were EMBASE and MEDLINE using the keywords and search sequences, inclusion and exclusion criteria and selection of abstracts provided in Appendix I (see Online Resource). The purpose of the literature review was to select and invite authors to the Delphi expert panel. To select the Delphi expert panel, corresponding authors whose names appeared at least once in the selected articles were listed. After screening for professions as well as any redundancies, those qualified (practicing spine professionals/specialists) were invited through e-mail to participate in the Delphi expert panel. In addition to these experts identified by review, the expert panel was further populated by inviting spine surgeons who are known to be opinion leaders in their respective regions or globally. Special emphasis was given to have the panel assembled of experts from all regions of the world be it underserved (Sub-Saharan Africa, Latin America, Asian subcontinent, Middle East) or adequately/over-served (North America, Europe, Australia, Japan).

Modified Delphi study

The Ethics Review Board of the Acibadem Ankara Hospital deemed this study exempt from human subjects review. The initial step of this study was to develop a questionnaire describing several clinical scenarios. The settings described were decided upon by authors based on their experience in the underserved as well as developed areas of the world. Five clinical scenarios were crafted for this study. Some scenarios refer to distinct locations as examples. These examples were provided so as to facilitate visualization of the setting described and do not necessarily specify only these settings/hospitals. The five clinical scenarios are as follows:

Scenario 1 You are in a clinic located in a village in an underserved area of the world. Example clinic location: Central Botswana, 22 km from a District Hospital Area. Service: this is considered a fairly large clinic in a village of 8000 inhabitants. Staff: 14 general practice nurses and 2 midwives. Staff nurse triages patients. One full-time medical officer manages a daily walk in clinic and anti-retroviral (ARV) clinic. Clinic is open 24 h. Outreach visits: monthly visits by a specialist physician and gynaecologist from District Hospital. Facilities: there is a makeshift maternity ward. No theatre. No X-ray machine and no CT scanner. No physiotherapy. Pharmacy: a host of painkillers and antibiotics are regularly stocked. Other services: one ambulance available for referrals to District Hospital.

Scenario 2 You are in a Level 1 District Hospital in an underserved area of the world. Example location: Central Botswana, 200 km from capital city, Gaborone. 225-bed capacity. Two medical wards, one surgical ward, three orthopaedic wards. Obstetric and psychiatry wards. Orthopaedic surgeons available, no neurosurgeons. Three orthopaedic wards; female orthopaedic ward: 25 bed capacity: average inpatient 40, male orthopaedic ward: 25 bed capacity: average inpatient 40 paediatric orthopaedic ward: 15, orthopaedic beds—average inpatient 15. Radiology: X-ray available. No CT or MRI scanner. No radiologist. Theatre: three fairly large theatres, two available for orthopaedic surgery, three minor theatres. Monthly theatre swabs and cleaning days. No spine table, available tables not translucent. One C-arm image intensifier. One anaesthetist and several anaesthetic nurses. ICU: non-functional, no trained staff and poorly equipped. Laboratory: basic tests, blood bank not available. No pathologist in-house. Pharmacy: pharmacy is well stocked (Opiates, NSAIDS, Gabapentin, Bisphosphonates, and various antibiotics). Various injectables. Other specialties: general surgeon, physician, three Gynaecologists. Emergency: trained paramedics available. Spine precaution is routinely practiced in trauma cases. No emergency medicine specialist. Physiotherapy: reasonably equipped physiotherapy unit, some full-time physiotherapists. Occupational therapy unit available. Well-equipped orthotics unit. Various spine braces available.

Scenario 3 You are in a Level 2 Referral Hospital in a reasonably served area in the world. Example location: Gaborone, Capital City. Tertiary institution. Largest public hospital in the country. Bed capacity 400. Orthopaedic facilities: four orthopaedic surgeons, mainly trauma. One performs spinal surgery. Three orthopaedic wards; female ward: 30 bed capacity, but average inpatient 50; male ward: 30 bed capacity, average inpatient 64; paediatric: 15 orthopaedic bed, average 15 patients. Neurosurgery facilities: 1 neurosurgeon, performs spinal surgery. No specific neurosurgery ward. No separate spine unit or ward. Spine rehabilitation centre supported by a charity organization. Sub-standard inpatient nursing care due to high patient/nurse ratio. Radiology: digital X-ray available. Helical CT scanner available. No MRI scanner in-house, MRI scan services outsourced. Three radiologists. Theatre: five major theatres, one for orthopaedic surgery, four minor theatres. Regular theatre cleaning

days with culture swabs. Limited trained theatre nurses. Two steam autoclaves. Experienced anaesthetic team. One C-arm image intensifier in theatre. Spinal implants available. ICU: 10 bed ICU with three ICU specialists. Well-equipped laboratory: advanced tests available. Blood bank and blood products such as fresh frozen plasma available. Pathologist available. Pharmacy: pharmacy is well stocked. Other specialties: General Surgery, Plastic Surgery, Urological Surgery, Medicine, Nephrology, Cardiology, Paediatrics. Emergency: emergency medicine specialist. Well-trained paramedic team. A/E medical officers have completed ATLS and ACLS courses. Physiotherapy: Physiotherapy unit, reasonably staffed but sub-standard equipment Orthotics unit: provides TLSO, Neck Collars and Lumbar braces only.

Scenario 4 You are in a Level 3 Private/University Referral Hospital in a reasonably served area of the world. Example location: 200-bed private hospital in Ankara, Turkey. Surgeons: three orthopaedic surgeons of whom one does some spine surgery. Two neurosurgeons doing limited spine surgery. Theatres: eight fairly large operating theatres, three have laminar air flow. High-quality theatre fluoroscopy machine is available. Good quality operating microscope available. ICU: ten bed ICU with full-time ICU interventionist. Radiology: in addition to the previous setting, a 1.5 T MRI and helical CT scanner. Other services: well-equipped cardiac catheterization facility. Laboratory: modern up to date laboratory, blood bank available. Physiotherapy: well-equipped and staffed Physiotherapy unit, various braces available. Pharmacy: well-stocked. Emergency: 24 h Accident and Emergency Unit Emergency physician available. Nursing staff: well-staffed hospital, no dedicated spine unit. Other Specialties: Vascular Surgery, Plastic Surgery, Psychiatry, Psychology, General Surgery, ENT Surgery, Medicine, Nephrology, Obstetrics, Paediatrics.

Scenario 5 You are in a Spine Centre of Excellence/Reference in any country. Spine Team: Neurological Surgeons, Orthopaedic Surgeons, Residents and Fellows. Spine Anaesthetic team. Theatre: state of the art theatre facilities. Spinal navigation, spine table available. High-resolution operating microscopes. Every wide spectrum of implants available. Intra-operative neuro-monitorisation 3-D intraoperative fluoroscopy. Well-trained theatre staff team. Bonebank facility in-house. ICU: state-of-the-art ICU facilities. Research and education: Well-staffed Spine Research lab available. Fellows and residents teaching days. Scheduled multi-disciplinary team meetings. Radiology: neuro-radiologists, interventional radiologists, multiple MRI scanners ± functional MR imaging, MR spectroscopy, PET and PET MR imaging. Nuclear medicine available. Radiotherapy available. Lab: advanced lab tests. Advanced blood bank. Pathology department. Others: various surgical and nonsurgical specialties available; pain physician specialists, pain nurse specialists, physical therapists, psychologists, neurophysiologists, dieticians.

Modified Delphi process

Round 1: Delphi questions' assessment

Five clinical scenarios were presented with three questions for each setting: (1) What diagnostic tests specific to spinal pathology (i.e. physical examination, neurological examination, imaging, blood tests, triage) can be performed in this scenario? (2) Within the same scenario, which non-invasive interventions/therapies (physical therapy and rehabilitation, chiropractic interventions, trigger point injections, etc.) can be performed? (3) Within the same scenario, which invasive interventions/therapies or surgeries (facet and/or epidural injections, biopsies, vertebroplasty/kyphoplasty, any open or minimally invasive surgeries, etc.) can be performed? Two questions were asked about the above questions: (1) Is this question understandable? (2) What can be done to improve this question or make it easier to understand? Answers provided to these questions by the panel were incorporated into the questions that would be used in rounds 2–4 of the consensus panel.

Round 2: initial collection of factors

The above-mentioned questions of round 1 were presented to the panel as open-ended questions and they were asked to provide a list of clinical evaluation, diagnostics and procedures that may be performed in the five given settings. Answers provided by individual panel members were compiled, evaluated and merged as a list of tests and procedures to form the basis of the third round on the feasibility as well as the safety of them. The phrase "… can be performed in this setting" was used to assess both the safety (can it be safely done?) and the feasibility (can it possibly be done?) of a given test/intervention.

Round 3: evaluation of factors

The panel was presented with the same questions 1–3 as listed above, using the same lists of tests and procedures per individual question for each separate setting and asked to rank the feasibility and safety of each individual test and procedure in that given setting on a scale from 1 to 9, with one denoting "least safe and likely" and nine denoting "most safe and likely". The results for this step were analysed with calculations of the median, first quartile, third quartile and interquartile range (IQR) for each factor feasibility and safety.

Round 4: re-evaluation

The purpose of round 4 was to offer a second decision opportunity to the Delphi expert panel so as to obtain a better agreement. In this final step, experts of the panel returned any modifications to previous answers.

Statistical analysis

Answers were compiled from round 2 and 3. The median, first quartile, third quartile and the interquartile range (IQR) were calculated for each test and procedure in the given five settings by an independent statistician. The expert panel was provided with the results and was asked whether they would change their scores per individual test and procedure. These final answers were then re-analysed with calculations of the median, first quartile, third quartile and IQR for each factor, any decrease between quartiles was accepted as an indicator of consensus, and were accepted as final. Any IQR smaller than 1.2 for any item was accepted as a "consensus (C)", whereas any IQR larger than 1.2 as "no consensus (NC) in accordance with Zeliff and Heldenbrand [15]. All statistical analyses were performed using SPSS 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.).

Results

Seventy-eight surgeons and spine experts were invited. Nineteen experts participated in the questionnaire for round 1, 14 of the 19 answered round 2, and 12 of the 19 responded in round 3 and in round 4. The panel members in rounds 3 and 4 were from USA (2), South Africa (2), India, Kenya, Argentina, Pakistan, Brazil, Spain, Malaysia and United Kingdom. The lead author personally knew all panel members and each had considerable experience on health care services in underserved areas either by virtue of the geographical locations or by providing care to people referred to them from underserved areas. Upon return of the questionnaires between rounds, five experts made slight modifications in their decisions whereas seven did not change their responses. The list of diagnostic modalities, non-invasive, and invasive procedures for spinal disorders as populated by the consensus in round 2 is presented in Fig. 1. The results at the end of the round 4 are presented in Table 1. A summary can be seen in Fig. 2.

Although the points of consensus are fairly heterogeneous for scenarios 2–4, emerging patterns are notable. Only simple diagnostic modalities are considered to be feasible and safe in the simplest (scenario 1, Table 1) with mostly no resources other than the clinical skills of the clinical personnel. There was 100% consensus that no invasive procedure

Diagnostic modalities

- Physical examination
- Neurological examination
- Basic blood and urine work
- Triage
- Identification of the Red Flags
- Identification of the Yellow flags
- Detailed blood and urine work (including hormone and tumour markers, Procalcitonin, Ig levels etc.)
- Osteoporosis and fracture risk assessment
- Detailed imaging (including CT and/or MRI, angiography etc.)
- Accurate mechanical stability assessment
- Accurate fracture classification
- Accurate tumour staging
- Accurate surgical risk assessment (consultations, cardiac evaluation etc.)

Non-invasive procedures

- Basic core strengthening exercises
- Skilful neglect and follow-up
- Physical therapy including traction and manipulation
- Chiropractic manipulation and interventions
- Prescription of pain killers (Acetaminophen and like)
- Prescription of NSAIDs (Diclofenac and like)
- Prescription of narcotic analgesics
- Prescription of osteoporosis treatment (Bisphosphonates and like)
- Medical treatment for infections (specific and non-specific)
- Chemotherapy
- Radiotherapy
- Trigger point injections
- Epidural injections (excluding selective nerve root blocks, including caudal blocks)
- Acute external immobilization and bracing (TLSO, collars, cranial traction and like)
- Elective external immobilization (Collars, TLSO, deformity braces and like)
- Post-surgery mobilization and rehabilitation

Invasive procedures including surgery

- Facet blocks / RF ablation
- Selective nerve root blocks
- Percutaneous or open biopsy
- Percutaneous tumour ablation (RF and like)
- Vertebroplasty / Kyphoplasty
- Discectomy (Lumbar or Cervical)
- Endoscopic discectomy / decompression
- Percutaneous / minimally invasive instrumentation (anterior and posterior)
- Acute decompression surgery (Infection, tumour, trauma)
- Acute stabilization and instrumentation (Infection, tumour, trauma)
- Elective decompression surgery
- Posterior instrumentation (excluding deformity surgery)
- Paediatric deformity surgery (excluding congenital and/or neuromuscular)
- Paediatric deformity surgery (Congenital and/or neuromuscular)
- Adult deformity surgery (including osteotomies)
- Anterior thoracolumbar surgery/instrumentation
- Tumour ablation and reconstruction (including sacrum)

Fig. 1 Diagnostic modalities, non-invasive, and invasive procedures as relevant to spine surgery

Table 1 Summary of the results

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Diagnostic modalities safety and feasibility [median (IQR)]					
Physical examination	9 (0)	9 (0)	9 (0)	9 (0)	9 (0)
Neurological examination	9 (0)	9 (0)	9 (0)	9 (0)	9 (0)
Basic blood and urine work		9 (0)	9 (0)	9 (0)	9 (0)
Triage		9 (0)	9 (0)	9 (0)	9 (0)
Identification of the red flags		9 (0)	9 (0)	9 (0)	9 (0)
Identification of the yellow flags			9 (0)	9 (0)	9 (0)
Detailed blood and urine work (including hormone and tumour markers, procalcitonin, Ig levels, etc.)	1 (0,25)		9 (0)	9 (0)	9 (0)
Osteoporosis and fracture risk assessment			9 (0)	9 (0)	9 (0)
Detailed imaging (including CT and/or MRI, angiography, etc.)	1 (0)	1 (0)	9 (0,5)	9 (0)	9 (0)
Accurate mechanical stability assessment	1 (0)			9 (0)	9 (0)
Accurate fracture classification	1 (0,25)		9 (0)	9 (0)	9 (0)
Accurate tumour staging	1 (0)		9 (0)	9 (0)	9 (0)
Accurate surgical risk assessment (consultations, cardiac evaluation, etc.)	1 (0)	5 (0)	9 (1)	9 (0)	9 (0)
Non-invasive procedures safety and feasibility [median (IQR)]					
Basic core strengthening exercises	9 (0,5)	9 (0)	9 (0)	9 (0)	9 (0)
Skilful neglect and follow-up		9 (0)	9 (0)	9 (0)	9 (0)
Physical therapy including traction and manipulation		9 (0,5)	9 (0)	9 (0)	9 (0)
Chiropractic manipulation and interventions			9 (0)	9 (0)	9 (0)
Prescription of pain killers (acetaminophen and like)		9 (0)	9 (0)	9 (0)	9 (0)
Prescription of NSAIDs (diclofenac and like)		9 (0)	9 (0)	9 (0)	9 (0)
Prescription of narcotic analgesics		9 (0,75)	9 (0)	9 (0)	9 (0)
Prescription of osteoporosis treatment (bisphosphonates and like)			9 (0)	9 (0)	9 (0)
Medical treatment for infections (specific and non-specific)			9 (0)	9 (0)	9 (0)
Chemotherapy	1 (0)	1 (0)		9 (0,5)	9 (0)
Radiotherapy	1 (0)			9 (1)	9 (0)
Trigger point injections			9 (0)	9 (0)	9 (0)
Epidural injections (excluding selective nerve root blocks, including caudal blocks)	1 (0)		9 (0)	9 (0)	9 (0)
Acute external immobilization and bracing (TLSO, collars, cranial traction and like)			9 (0)	9 (0)	9 (0)
Elective external immobilization (Collars, TLSO, deformity braces and like)		9 (0)	9 (0)	9 (0)	9 (0)
Post-surgery mobilization and rehabilitation		9 (0)	9 (0)	9 (0)	9 (0)
Invasive procedures including surgery safety and feasibility [median (IQR)]					
Facet blocks/RF ablation	1 (0,5)		9 (0)	9 (0)	9 (0)
Selective nerve root blocks	1 (0,5)		9 (0)	9 (0)	9 (0)
Percutaneous or open biopsy	1 (0,5)	7 (0)	9 (0)	9 (0)	9 (0)
Percutaneous tumour ablation (RF and like)	1 (0)			9 (0)	9 (0)
Vertebroplasty/kyphoplasty	1 (0)			9 (0)	9 (0)
Discectomy (lumbar or cervical)	1 (0)		9 (0,25)	9 (0)	9 (0)
Endoscopic discectomy/decompression	1 (0)			9 (0)	9 (0)
Percutaneous/minimally invasive instrumentation (anterior and posterior)	1 (0)			9 (0)	9 (0)
Acute decompression surgery (infection, tumour, trauma)	1 (0)			9 (0)	9 (0)
Acute stabilization and instrumentation (Infection, tumour, trauma)	1 (0)		9 (1)	9 (0)	9 (0)
Elective decompression surgery	1 (0)		9 (0)	9 (0)	9 (0)
Posterior instrumentation (excluding deformity surgery)	1 (0)		9 (0)	9 (0)	9 (0)
Paediatric deformity surgery (excluding congenital and/or neuromuscular)	1 (0)			9 (0)	9 (0)
Paediatric deformity surgery (congenital and/or neuromuscular)	1 (0)				9 (0)
Adult deformity surgery (including osteotomies)	1 (0)				9 (0)
Anterior thoracolumbar surgery/instrumentation	1 (0)			9 (1)	9 (0)
Tumour ablation and reconstruction (including sacrum)	1 (0)		3 (0)		9 (0)

Scores with consensus for diagnostic modalities and procedures for all clinical settings [median (IQR)]. On the scale of scores, 1 represents "Totally unsafe or infeasible", 5 "Uncertain", and 9 "Totally safe and feasible"

- **Level 5 = Specialized spine center.**
All diagnostics and therapeutic activities are safe.

- **Level 4 = University hospital setting with departments of orthopaedics and neurosurgery.**
Most procedures are deemed safe. No consensus was achieved for complex deformity surgeries and complex tumor ablations.

- **Level 3 = A setting equivalent to a city general hospital.**
Most diagnostic procedures, non-surgical treatment modalities and basics surgeries (ie, decompression and stabilization) are deemed safe.

- **Level 2 = A setting equivalent to a district hospital.**
A few non-invasive procedures may be performed. No consensus was achieved on the safety and feasibility of all invasive procedures and some non-invasive modalities, such as treatment of infections, and prescriptions for osteoporosis.

- **Level 1 = Rural clinic setting.**
No invasive procedures are recommended as they are deemed unsafe and unfeasible. No consensus was achieved for non-invasive procedures in this setting.

Fig. 2 Summary table of surgical spine care recommendations

was feasible and safe in this setting. On the other extreme, all procedures (diagnosis, staging, and treating spinal disorders) appear to be feasible and safe in a specialized spine center (scenario 5, Table 1). Accurate diagnostic workup was deemed feasible and safe in lower levels of complexity (from scenario 3 upwards, Table 1) compared to non-invasive procedures (scenario 4, Table 1) and the full range of invasive procedures (scenario 5, Table 1). For responses to please see Supplementary Appendix II Tables 1 through 15 in Online Resources.

Discussion

This study aimed to analyse the existing knowledge base on the surgical care of spinal disorders in underserved areas of the world and to stratify surgical care to provide guidance on which services may be feasible and safe for particular levels of care. The results of this study suggest which non-invasive to invasive spine procedures can be done in the upper and lower extremes of the settings and resources available for levels of care. Limited resources restrict interventions for the intermediate scenarios described.

This study offers guidance to groups for planning and executing surgical spine care by providing recommendations for optimal resource utilization. It has been an observation of the authors of this study that people planning and managing health care for spinal disorders are not necessarily versed in the terminology or potential stratification of care. The problems associated with the lack of awareness range from waste of essential funds to exposure of patients with spinal disorders to unnecessary risks and complications. On one hand, decision makers in some areas may expect complex surgery to be performed at lower level settings, which demonstrates an unawareness of the spectrum of complexity of surgical care, whereas highly trained surgical personnel in higher resource settings may be expected to perform triage, which demonstrates a waste of resources. It is easy to understand the danger associated with the expectation of "over-performance" but the necessity of the highly trained personnel to perform basic tasks is also as dangerous as it has the potential to create an environment in which the responsibility for all spinal care is given to spine surgeons, which may cause a permanent state of under-performance in them. Although some may argue that underperformance may eliminate the element of danger; it has the potential of causing major problems including: (1) spinal care disappears from the settings that are accessed by the majority of the population; and (2) it becomes so expensive that the health care providers grow reluctant to provide good quality spinal care.

We found consensus at the extremes of the feasibility and safety scale (Table 1). This table demonstrates an abundance of scores of 1 (not feasible and safe at all) and 9 (completely safe and feasible) and almost no other scores (there is one score of 3 and another of 5). This may arise from the geographical diversity of the members of our consensus panel, from Asian subcontinent to Europe to North America to Latin America. In some parts of the world, spine care is provided mostly by specialized spine centers and in other areas mostly under-qualified health care personnel provide care. Our results suggest this diversity has a large grey zone of dos and don'ts in the intermediate settings, in which experts from underserved areas may appear more prone to considering more procedures performed in lower settings as safe and the experts from the relatively well-served areas, the opposite. We believe that this diversity of opinion is not a shortcoming but rather a strength.

Our results suggest what surgical procedure can be safely performed and where. There was agreement that almost no surgery may be safe and feasible at the primary care setting apart from detailed physical and neurological examination. It is interesting that even triaging a patient with a spinal disorder was not considered feasible uniformly at the primary care level (see Online Resource Table 1 in the Supplementary Appendix II). The reason for this may hinge on the diversity of the panel as discussed above and could be associated with the absence of any laboratory or imaging facilities in low-resource settings. This finding suggests that sending surgical personnel into rural primary care settings without the support

of essential resources does not necessarily constitute a rational use of these personnel, as it does not eliminate the necessity of referrals to higher levels of care even for tasks as primary care and as essential as triaging. Our findings suggest that medical personnel with only hands and judgment are not considered better than nothing, at least for surgical spinal disorders. For intermediate levels (scenarios 2 and 3) there was consensus that triaging and diagnosis may be performed with increasing safety, from the identification of the yellow and red flags in scenario 2 to almost all diagnostic procedures in scenario 3. The difference between these two settings lies in the domain of invasive procedures, for which almost nothing is considered safe and feasible in scenario 2 versus all emergency and pain-related procedures (i.e. surgical decompression and stabilization procedures) being deemed safe. Higher level settings appeared to be different only in the domain of complex reconstructive surgeries, such as complex deformity surgery and tumour ablation/reconstruction.

These findings demonstrate that the stratification proposed could be effective in identifying incrementally increasing levels of complexity of surgical care. In addition, the traditional three-level stratification of medical care (from primary to tertiary) may not necessarily be applicable to the surgical care of spinal disorders. For example, an underlining disparity was seen between the fourth and fifth levels. Albeit seemingly small, this difference demonstrates that: (a) the majority of cases may be handled by the "tertiary level" medical institutions so there may be a need to build only a limited number of highly specialized centers in areas low in resources; and (b) not every surgical procedure can be safely performed in the "tertiary level" centers, so there is a need for well-planned and constructed specialty care centers. Our study suggests a need to further divide the existing three-level medical care stratification for surgery into five, especially in the underserved areas of the world.

Strengths

This is the first study that addresses and discusses stratification of spinal care and centers. We think this is important in the present era of having higher technologies being implemented in spine care that in turn increase the diversity in care. This is also the first study to address surgical spine care in underserved areas using a modified Delphi methodology. It is our belief that this study provides an ideal level of geographical and cultural diversity to address these issues. The participants decided on whether the questions were understandable, and what items on the list were included, thereby decreasing the risks of having potentially important items being misunderstood or left out unintentionally.

Limitations

Potential limitations of a Delphi process includes a lack of solid definitions for consensus, reliance upon participant dedication and communication skills (i.e. linguistic), time constraints, and response rates. The findings of this Delphi represent only the members who were invited and the 19 who agreed to participate, thus is limited to the expert opinions of these people. It is possible that different results could have occurred with a different set of participants or with a larger group of experts. The panel was limited by specialty representation, in that a more broad set of provider types and specialties could have been included and may have resulted in different recommendations. We did not account for the non-responders, which may have influenced our results in that valuable or dissenting opinions were not included because they did not participate. Further, the modified Delphi procedure we used provided only expert consensus level of evidence. We chose this process because we were introducing a new stratification.

Future work

Developing a stratification scheme alone does not solve the problem of resource utilization. Therefore, future research is needed, which includes validation of the proposed scheme in the utilization in Spinal Surgery and evaluation of its use for improvements in surgical spine care outcomes in underserved areas. These goals may be achievable since implementation does not necessarily need any further infrastructure to apply the stratification.

Conclusion

The consensus panel proposed a five-level stratification scheme for surgical care of spinal disorders, levels ranging from a rural clinic in an underserved area to a specialist spine centre. Diagnostic and therapeutic procedures that were perceived to be safely and effectively performed at each level were recommended. This stratification is hoped to provide valuable guidance to health care providers, especially in medically underserved areas and low- and middle-income countries.

Compliance with ethical standards

Funding The Global Spine Care Initiative and this study were funded by Grants from the Skoll Foundation and NCMIC Foundation. World Spine Care provided financial management for this project. The funders had no role in study design, analysis, or preparation of this paper.

Conflict of interest EAc declares grants: Depuy Synthes Spine, Medtronic; speaker's bureau: AOSpine, Zimmer Biomet. TM de-

clares fellowship grant-Medtronics. SY declares no COI. SA declares no COI. MN declares funding from Skoll Foundation and NCMIC Foundation through World Spine Care. Co-Chair, World Spine Care Research Committee. Palladian Health, Clinical Policy Advisory Board member. Book Royalties Wolters Kluwer and Springer. Honoraria for speaking at research method courses. KR declares funding to UOIT from Skoll Foundation, NCMIC Foundation through World Spine Care. SH declares funding to UOIT from Skoll Foundation, NCMIC Foundation through World Spine Care. Clinical Policy Advisory Board and stock holder, Palladian Health. Advisory Board, SpineHealth.com. Book Royalties, McGraw Hill. Travel expense reimbursement—CMCC Board.

Appendix: Consensus Panel

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Consensus panel
MG declares no COI.
AA declares no COI.
EM declares AO Spine Africa Faculty courses—honorarium.
NFJ declares no COI.
JE declares no COI.
RD declares no COI.
CCW declares no COI.
EV declares no COI.
TB declares European Spine Journal provided a grant to investigate scoliosis.
JPF declares no COI.

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