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Gianpaolo Tomaselli**
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PATIENT SAFETY: DELIVERING COST-CONTAINED, HIGH QUALITY, PERSON-CENTERED, AND SAFE HEALTHCARE

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Editorial: Patient Safety: Delivering Cost-Contained, High Quality, Person-Centered, and Safe Healthcare

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World Health Organization defines patient safety as the absence of preventable harm and the prevention of errors/adverse events in healthcare (1). Despite stakeholders' unanimous consideration that patient safety is a vital principle of healthcare delivery, it remains a concern across health systems worldwide. Across the continuum of healthcare, every process is potentially subjected to adverse events, which may originate from faults/errors in clinical and operational practices, products, procedures, or systems.

This Research Topic reflects the complexity facing patient safety. It also reflects on the challenges involved in delivering cost-contained, high quality, person-centered, ethically sound, and safe healthcare. The contributions project the complexity and multidimensionality of patient safety by highlighting its facets. These include healthcare managers' and leaders' role in prioritizing safety climate for better patient outcomes, and the importance of innovation and new technologies in medicine to drive the patient safety agenda, which in turn leads to the debate of economic efficiency by containing costs through error minimization and waste reduction. The topic discusses the use of complementary and alternative therapies, as well as over-the-counter drugs—which a closer look reveals that these day-to-day practices cannot be ignored. Patient safety also depends on smart decision-making processes and ethical provider-patient relationships. The articles can be grouped into: (i) the role of leadership in ensuring safety climate and clinical performance; (ii) economic efficiency, innovation, and new technologies; (iii) complementary and alternative medicine; (iv) decision-making; and (v) ethics.

Teuma Custo et al. analyze the mediating role of managerial safety practices and priority of safety in the relationship between safety climate and safety performance in intensive care. Their results highlight the suitability of safety procedures, as well as the saliency of the clarity and unambiguity of clinical/managerial information flow. The leader's role is that of being visibly supportive (2) as a safety referent and change agent by prioritizing safety. Safety leaders need to emerge so as to ensure healthcare organizations' ongoing commitment to patient safety.

Three articles deal with economic efficiency, innovation, and new technologies. von Eiff et al. demonstrate that size-specific instrumentation sets contribute to improved operating room's efficiency. Furthermore, Wienert's article debates Health Information Technologies' (HIT) impact on reducing costs while sustaining patient safety. This contribution also considers HIT interventions' adverse effects and implementation failures. In addition, Gong et al. earmark trust, subjective norm, perceived benefit, and persisting habits to achieve providers'/users' confidence in adopting patient-safe online consultation services.

The use of complementary/alternative medicine, and over-the-counter drugs suffers from lack of scientific evidence. Indeed to ensure patient safety, Luketina-Sunjka et al. argue in favor of investigating and regulating their use.

Two articles focus on the process of decision-making so as to manage patients safely. Micieli and Kingston propose an evidence-based flowchart that identifies headache patients needing neuroimaging. These flow-charts, while allowing flexibility at the discretion of professional experts, reduce the degree of variation in case management and enhance decision-making clarity. Lu et al.'s review focuses on shared decision-making, with "Informed consent," "Surgery," "Depression," "Older adult," and "Patient-centered care" being the most researched areas. The article by Lu et al. also highlights the value of patient-centered care which links very well with the articles by Chan et al. and Tomaselli et al., with the latter emphasizing the shift toward person-centered care.

From an ethical perspective, Chan et al. show challenges that clinicians face in family practice. Practitioners are becoming more versed at looking for hidden agendas during consultations, which if missed may result in unsafe therapeutic management—in particular involving issues that patients may not be comfortable disclosing spontaneously or at the first encounter. Therefore, by adopting the biopsychosocial model of care, clinicians are better able to reach correct diagnoses, and to identify "hidden" issues similar to that identified by Chan et al., namely family violence, which may indeed be the cause of ill-health. This of course takes the discourse of patient safety to

family practice and away from the more commonly researched hospital context.

Tomaselli et al.'s scoping review considers person-centered care from an ethical perspective as distinct from the doctor-patient discourse considered in relational ethics and patient-centered care. The patient is a person and a partner in care with capabilities and resources. It follows earlier work on PCC within corporate social responsibility (3).

In conclusion, this topic portrays patient safety through different lenses and positions itself as an eclectic subject. The importance of this collection lies in the diversity of the contributions which will assist the reader to appreciate the various facets of patient safety. While patient safety was, is, and will remain a topic of immense importance to healthcare, the debate in the future should venture into emerging issues. Future debates should consider patient safety issues in population aging and migration (4), burnt-out professionals (5, 6), technology use (7), point-of-care testing (8), the influence of type of health system on healthcare innovation and therefore on quality improvement (9), and the use of hospital performance dashboards (10) for better visibility of information from bedside to board (11) so as to ensure safety in communication. It is indeed the scope of this research topic to attract the readers' interest and to keep the debate on patient safety alive.

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SB led the group of editors for this Research Topic. All authors contributed to the article and approved the submitted version.

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REFERENCES

1. World Health Organization. *Conceptual Framework for the International Classification for Patient Safety Version 1.1: Final Technical Report January 2009*. World Health Organization (2010).
2. Buttigieg SC, Cassar V, Scully JW. From words to action: visibility of management in supporting interdisciplinary team working in an acute rehabilitative geriatric hospital. *J Heal Organ Manage*. (2013) 27:618–45. doi: 10.1108/JHOM-06-2012-0101
3. Buttigieg SC, Tomaselli G, Byers V, Cassar M, Tjerbo T, Rosano A. Corporate social responsibility and person-centered care: a scoping review. *J Glob Responsib*. (2019) 10:289–306. doi: 10.1108/JGR-01-2019-0006
4. Jakovljevic MM, Netz Y, Buttigieg SC, Adany R, Laaser U, Varjadic M. Population aging and migration – history and UN forecasts in the EU-28 and its east and south near neighborhood – one century perspective 1950–2050. *Global Health*. (2018) 14:30. doi: 10.1186/s12992-018-0348-7
5. Williams ES, Rathert C, Buttigieg SC. The personal and professional consequences of physician burnout: a systematic review of the literature. *Med Care Res Rev*. (2019). doi: 10.1177/1077558719856787
6. Buttigieg SC, Azzopardi E-A, Cassar V. The mediating role of burnout in the relationship between perceived patient-safe, friendly working environment and perceived unsafe performance in an obstetric unit. In: Moffatt-Bruce S, editor. *Structural Approaches to Address Issues in Patient Safety (Advances in Health Care Management, Vol. 18)*. Somerville, MA: Emerald Publishing Limited (2019). p. 99–118. doi: 10.1108/S1474-823120190000018005
7. van Zaalén Y, McDonnell M, Mikolaj B, Buttigieg S, Requena Hernandez MC, Holtkamp F. Technology implementation in delivery of healthcare to older people: how can the least voiced in society be heard? *J Enabling Technol*. (2018) 12:76–90. doi: 10.1108/JET-10-2017-0041
8. Buttigieg SC, Von Eiff W, Farrugia P, Von Eiff MC. Process optimization in the emergency department by the use of point-of-care-testing (poc) in life-threatening conditions: comparative best practice examples from Germany and Malta. *Adv Health Care Manage*. (2015) 17:195–219. doi: 10.1108/s1474-823120140000017012

9. Buttigieg SC, Gauci D. Health care innovation across health systems. In: Gurtner S, Soye K, editors. *Challenges and Opportunities in Health Care Management*. Cham: Springer (2015). p. 47–59. doi: 10.1007/978-3-319-12178-9_4
10. Buttigieg SC, Pace A, Rathert C. Hospital performance dashboards: a literature review. *J Heal Organ Manage*. (2017) 31:385–406. doi: 10.1108/JHOM-04-2017-0088
11. Pace A, Buttigieg SC. Can hospital dashboards provide visibility of information from bedside to board? A case study approach. *J Heal Organ Manage*. (2017) 31:142–61. doi: 10.1108/JHOM-11-2016-0229

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An Approach to Identifying Headache Patients That Require Neuroimaging

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Headache is one of the most common clinical scenarios faced by a neurologist or neurologist in training. However, the decision process on when to complete neuroimaging can be difficult in clinical practice. This article focuses on a well-organized and evidence-based approach to identify patients with headache that require neuroimaging and will lend confidence to the clinician faced with these scenarios in clinical practice. The approach includes neuroimaging in episodic migraine, chronic migraine, identifying secondary headache disorders in clinic and the emergency department, and discusses pitfalls to over imaging. The article concludes with a flowchart to summarize an overall clinical approach.

Keywords: neuroimaging, headache, neurology, migraine, MRI

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INTRODUCTION

A framework for when to complete neuroimaging in patients with headache is an important skillset for a neurologist, neurologist in training, emergency physician, internist, or general practitioner. Simply, when is it appropriate to order neuroimaging? Does the patient with chronic migraine require a magnetic resonance imaging (MRI) study? What imaging does a patient with a thunderclap headache require in the emergency department? When is vascular imaging indicated? What are characteristics of neurological symptoms to suggest it is secondary to a focal cerebral lesion as opposed to a migraine aura?

The reality of clinical practice is patients are often over imaged for fear of missing uncommon but important intracranial pathology. Physicians may also feel compelled or pressured to complete imaging, when the likelihood of finding intracranial pathology may be the same as the general population. There are potential risks to the patient and society with this approach in a resource-restricted health care system.

There are no available studies that allow for definitive recommendations on neuroimaging in headache patients, however this article will focus on an evidence-based and well-organized approach and will lend confidence to the physician faced with these common scenarios in clinical practice. The authors created a flowchart (see **Figure 1**) that may be helpful as a general clinical approach. It can be applied to a broad patient demographic including patients seen in clinic, the emergency department, and the inpatient hospital ward.

NEUROIMAGING IN MIGRAINE

Primary headache (i.e., migraine and tension headache) are the majority of headache patients presenting to a primary care practice, 76% of which are migraine (1). Migraine is the third most prevalent disorder worldwide and second most disabling, affecting more women than men (2).

According to the *International Classification of Headache Disorders, 3rd Edition* (ICHD-III) criteria, migraine attacks should last between 4 and 72 h, and have at least two of the four following criteria: (1) unilateral location, (2) pulsating pain, (3) moderate to severe intensity, and (4) aggravated by routine physical activity (3). There must also have at least one of the following: (1) nausea and/or vomiting and (2) photophobia and phonophobia.

Approximately 0.1% of headaches are sinister (i.e., secondary headaches, which include neoplasm, aneurysm rupture, venous sinus thrombosis, meningitis, etc.) (4). Among patients with migraine and a normal neurological examination, the prevalence of significant intracranial abnormalities on neuroimaging ranges from 0 to 3.1% and combining this data in a meta-analysis resulted in a prevalence of 0.18% (4). Specifically, the prevalence of arteriovenous malformations is 0.8% and saccular aneurysms is 2.4% on autopsy. Although there are many causes of secondary headache, clinical cues to their diagnosis will be present on history and neurological examination which will be discussed below.

In 1994, the American Academy of Neurology (AAN) created a guideline for the use of neuroimaging in patients with headaches and a normal neurological examination, which has not changed over the years (5). The AAN consensus concluded “in adult patients with recurrent headaches that have been defined as migraine, including those with visual aura, with no recent change in pattern, no history of seizures, and no other focal neurological signs or symptoms, the routine use of neuroimaging is not warranted.” The most common abnormalities found on MRI in migraineurs are white matter lesions localized in the subcortical or periventricular white matter best seen on fluid-attenuated inversion recovery (FLAIR) images, reported in 12–48% of migraineurs compared with 2–11% of control subjects (6). These lesions are non-specific and can be misinterpreted as signifying an inflammatory disease, such as multiple sclerosis, leading to patient anxiety, and further investigations, such as a lumbar puncture (with its associated risks). If atypical headache features are present and the patient does not meet ICHD-III criteria for migraine, a lower threshold for neuroimaging may be applied.

Visual aura may precede the migraine, or may not be followed by a headache in the case of migraine aura without headache. Diagnostic features of a visual aura include features such as propagation of a scintillating scotoma, zig-zag lines, fortification spectra, or photopsia. These positive visual symptoms may be a result of a migraine, but very rarely could be attributable to a focal seizure or occipital lobe ischemia (7). There are key clinical features of positive visual phenomenon that warrant neuroimaging to rule out an occipital lobe lesion (such as a cavernoma or AVM) (8). These include: a stereotypical visual aura that is repeatedly experienced in one hemifield, an increase in frequency or change in pattern of a longstanding visual aura, a sudden alteration in aura characteristics, any unexplained visual field defect and/or subjective persistence of a scotoma following a typical visual aura, or co-existence of seizures. If any of the above criteria are met, then neuroimaging with an MRI is indicated.

A CASE OF TRANSFORMATION FROM EPISODIC TO CHRONIC MIGRAINE

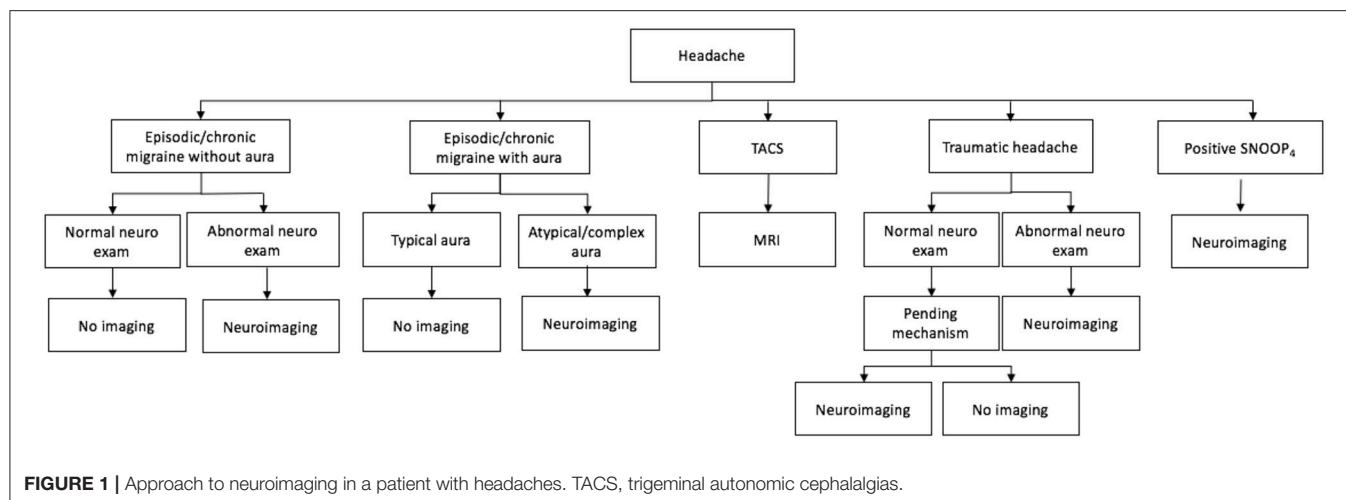
A 35-year-old female with a history of rheumatoid arthritis and episodic migraine without aura, treated with ibuprofen and Sumatriptan presents to family medicine clinic with increased frequency of migraine episodes over the last 6 months. In the last few months they are also occurring upon waking in the morning. Her migraines are now approximately 20 days per month and she is using Sumatriptan more than usual. Her rheumatoid arthritis is active and she is using Ibuprofen almost nightly for pain relief. Her baseline migraine frequency is 4–6 days per month. She is referred to the Headache clinic with a documented normal examination and a recently completed brain CT scan that is unremarkable. Did this patient require a CT scan? Do they now require a brain MRI?

To make a diagnosis of chronic migraine a patient needs to have headaches for ≥ 15 days per month (for >3 months) with migraine features present for ≥ 8 days (3). Transformation from episodic to chronic migraine occurs in $\sim 3\%$ of migraine patients per year (9). Analgesia overuse is a major risk factor for this transformation. Patients who overuse analgesia are at risk for medication overuse headache (MOH) where the analgesia leads to the paradoxical effect of increasing headache frequency. This is likely the cause of increased migraine frequency in the above example. Maximum monthly use of a non-steroidal anti-inflammatory is 15 days per month, which was exceeded by the patient in the above case (3). Maximum monthly use of a Triptan is 10 days per month. Treatment of MOH is beyond the scope of this paper, however recognition of this phenomenon is important as this patient did not require neuroimaging with a clinical history consistent with a known primary headache disorder, MOH and a normal documented neurological examination and absence of red flags.

In a study of 373 patients with chronic headache referred to a tertiary referral center for increased severity of symptoms or resistance to appropriate drug therapy, change in characteristics or pattern of headache, or family history of an intracranial structural lesion, only 1% (4 scans) showed significant lesions—two osteomas, one low grade glioma, and one aneurysm (10). Of these patients, only the aneurysm was treated. If a patient with headache presents to a primary care clinic with increased frequency of headache (rather than a change in headache characteristics), then a detailed history should be performed to investigate for possible internal or external precipitating factors, such as increased stress/anxiety, sleep deprivation, dietary changes (changes in diet, increased caffeine intake, or caffeine withdrawal), compliance with headache preventive medications, medication overuse or head trauma.

CLUES ON HISTORY FOR A SECONDARY HEADACHE DISORDER

Every headache history/exam should attempt to elicit red flags or worrisome clinical features that may signify the presence of an underlying pathological condition requiring neuroimaging. A commonly used published acronym is



SNOOP₄ (see **Table 1**) (11). If these features are addressed, the chance of overlooking a sinister cause for headache are greatly diminished. MRI is preferred over CT scan, however in the acute setting, especially in the emergency department a CT scan could be performed first, depending on the patient's symptoms. MRI is more sensitive, particularly for lesions in the posterior fossa, as well for neoplasms, cervicomedullary lesions, pituitary lesions, intracranial hyper/hypotension, and vascular disease (arterial and venous infarctions) (12).

Firstly, onset of maximum pain is important. A thunderclap headache ("worst headache of my life"), by definition reaches its maximum intensity within 1 min or less. It has an associated differential diagnosis, of which the most worrisome is bleeding into the subarachnoid space from a ruptured cerebral aneurysm (13). An urgent plain CT head should be performed looking for blood in the subarachnoid space, and if negative a lumbar puncture is indicated. However, these investigations are insufficient for a patient presenting with a thunderclap headache to the emergency department. Although it is sensitive enough to exclude a subarachnoid hemorrhage, vascular imaging with a CT angiogram +/- a CT venogram is warranted to investigate for other possible thunderclap headache etiologies such as reversible cerebral vasoconstriction syndrome (RCVS), or other less likely possibilities including vasculitis, cervical artery dissection, or cerebral venous thrombosis. CT angiogram is more sensitive than MR angiogram (12). Vascular imaging should be done in the case of a thunderclap headache, a family history of aneurysms or headaches that are continuously ipsilateral or progressive in nature. New onset headaches or change in headache characteristic/pattern in patients on anticoagulation warrants an MRI, specifically with gradient-echo sequence that is sensitive for hemosiderin and calcification, to assess for cerebral microhemorrhages.

An abnormal finding on neurological examination triples the odds of finding a significant intracranial abnormality on neuroimaging, although the odds are still low (i.e., <3 in 100) (4). A history of headache worsening with valsalva maneuver

significantly increased the odds of findings a significant intracranial abnormality on neuroimaging, particularly a Chiari malformation.

Intracranial hemorrhage, meningitis, and cerebral neoplasm rarely present with headache as their sole presenting symptom (12). Instead they may present with other focal neurological deficits, fever, laboratory signs of infection, known primary malignancy or constitutional symptoms that suggests a secondary cause of headache. These patients should be initially investigated with a CT head and then MRI if necessary. Identifying secondary headaches in patients over the age of 50 is clinically challenging. Importantly, only ~2% of migraineurs have their first headache over the age of 50 (12). In patients over the age of 65 who present to neurologists with new-onset headache up to 15% may have serious pathology such as stroke, giant cell arteritis, neoplasm, or subdural hematoma (14).

Cerebral venous sinus thrombosis (CVST) must be considered in the right clinical context. This includes, patients with hematologic prothrombotic states (i.e., antithrombin III deficiency, protein C or S deficiency, antiphospholipid antibody syndrome etc.), malignancy (especially hematological malignancy) pregnancy and puerperium, high risk medications (oral contraceptive pill), infections, and systemic diseases (lupus, inflammatory bowel disease, Behcet disease, etc.) (15). The headache in CVST is most often secondary to increased intracranial pressure secondary to impaired venous drainage. Headache may be the only symptom, so vigilance and clinical suspicion is important. CVST may present as a thunderclap headache, a progressive headache over days or weeks despite conservative management, or as an atypical headache. A plain CT scan of the head will miss many cases. Only one third of CVST demonstrates direct signs on CT head (i.e., hyperdense vessel or delta sign) (15). Venous imaging (CT venogram or MR venogram) must be ordered to assess the venous system. Invasive imaging with cerebral angiography should be reserved for cases where CT venogram or MR venogram is inconclusive or when an endovascular procedure is being considered.

TABLE 1 | Commonly used acronym to that may signify the presence of an underlying pathological condition requiring neuroimaging.

	Stands for	Example	Differential diagnosis
S	S ystemic symptoms	Fever, weight loss, fatigue	Infection (meningitis, encephalitis), giant cell arteritis, metastases, leptomeningeal carcinomatous
	S econdary risk factors	Malignancy, immunosuppression, HIV	
N	N eurologic symptoms/signs	Focal neurologic deficits, altered consciousness, confusion	Mass lesion, stroke, hydrocephalus
O	O nset	Thunderclap, abrupt	Most common include: subarachnoid hemorrhage, reversible cerebral vasoconstriction syndrome, pituitary apoplexy, cerebral venous sinus thrombosis, vasculitis
O	O lder (especially >50 years)	New onset, progressive headache	Mass lesion, giant cell arteritis
P	P ositional	Change lying vs. sitting	Intracranial hypotension
	P rior	Different in quality from baseline	Mass lesion
	P apilledema	Visual obscurations	Idiopathic intracranial hypertension
	P recipitated by	Valsalva, coughing, sneezing	Posterior fossa lesion

Headache is the most common presenting symptoms of idiopathic intracranial hypertension (IIH) or also known as pseudotumor cerebri, however the headache is variable and non-specific (16). Some patients describe headache exacerbation with changes in posture. The often refractory nature of the headache is a clinical cue, in the right patient demographic (i.e., overweight women of childbearing age). Tinnitus and transient visual obscurations lasting seconds often accompany the headache, occurring in two-thirds of patients with papilledema (16). An MRI brain with gadolinium and MR venogram should be ordered to rule out other potential intracranial pathologies, meningeal process or venous thrombus and secondly looking for radiographic signs of raised intracranial pressure (empty or partially empty sella, prominent subarachnoid space around the optic nerves, vertical tortuosity of the optic nerves, intraocular protrusion of the optic nerve head, venous sinus stenosis, and slit-like ventricles) (17). Contrary, low-pressure headache, or headache caused by reduced intracranial cerebral spinal fluid pressure (i.e., intracranial hypotension) can be caused by trauma (even trivial trauma), lumbar puncture, craniotomy, or spontaneously in patients with connective-tissue disorders. In some cases, spontaneous intracranial hypotension may be entirely cryptogenic. The headaches of intracranial hypotension are positional (relieved by lying down). MRI brain findings most often seen include brain descent, caudal displacement of the tonsils, diffuse pachymeningeal enhancement, and bilateral subdural fluid collections (12). MRI brain and spine with contrast should be ordered, and at times identification of the leak is seen.

Giant cell arteritis (GCA) is an inflammatory disease of medium and large vessels. The most feared complication is irreversible vision loss with involvement of the fellow eye if not recognized quickly. Although most clinical manifestations are non-specific, headache is the most common symptom, occurring in more than two-thirds of patients (18). The headache has no specific defining characteristics. An erythrocyte sedimentation rate (ESR) and c-reactive protein (CRP) should both be ordered in these patients, since ESR may be normal in up to 16.6% of biopsy-proven GCA patients (19). An MRI can be used to

investigate the mural thickness, contrast enhancement and lumen diameter of the temporal artery (20).

Patients with trigeminal autonomic cephalalgias (TACS), characterized by unilateral head pain associated with prominent ipsilateral cranial autonomic features (lacrimation, conjunctival injection, rhinorrhea) require an MRI brain once at initial presentation to exclude intracranial pathologies accounting for their “side-locked” headache. Pituitary and peri-pituitary gland pathology can present phenotypically as a TACS (21). Examples of TACS include cluster headache, paroxysmal hemicrania, short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT), short-lasting unilateral neuralgiform headache attacks with cranial autonomic symptoms (SUNA), and hemicrania continua (3). Any “side-locked” headache (i.e., headache always on the same side) should be imaged once, preferably with an MRI, to exclude an ipsilateral intracranial lesion.

Headache is often the most common sequelae from head injuries (22). For most individuals a traumatic headache gradually dissipates over several days, weeks, or months. In the acute setting, any focal neurological symptoms or signs immediately following a head injury should be promptly evaluated with a CT head and CT angiogram of the head and neck vessels to assess for the presence of a subdural or epidural hematoma, carotid or vertebral artery dissection, cerebrospinal fluid leak or rarely CVST or carotid-cavernous fistula (22). Bone windows should be included with the plain CT head to assess for fractures at the vault or base of the skull. In the absence of findings on the neurological examination, different imaging rules or guidelines have been adopted such as the CT head rules (23). In the chronic post-traumatic setting (weeks, months, or years) for patients with persistent headache with or without postconcussive symptoms, no diagnostic evaluation guidelines exist. MRI is more sensitive and should include a gradient weighted sequence to identify the presence of hemosiderin deposition. Other neuroimaging technologies such as diffusion tensor imaging, magnetic transfer imaging, magnetic source imaging, magnetic resonance spectroscopy,

and functional magnetic resonance imaging are currently being investigated (22).

WHEN TO ORDER NEUROIMAGING WITH CONTRAST

Gadolinium-containing contrast agents are often used in MRI to enhance the quality of images (10). Care is needed in patients with impaired renal function to avoid the rare, but serious adverse effect of nephrogenic systemic fibrosis. Headache patients that require MRI with gadolinium include: patients with abnormal neurologic examination, positional headaches, exertional or valsalva maneuver-exacerbated headaches, cluster or neuralgia-type headaches or facial pain, and known history of cancer, AIDS, immunocompromised, or infectious disease (12).

PITFALLS TO OVER IMAGING

“Therapeutic scans” may be appreciated by patients and their families, however it can complicate and confuse the situation. One of the difficulties with ordering MRIs in headache patients is the relatively high frequency of “false positive studies” or incidental findings, and in inexperienced hands can be misinterpreted for the cause of the patient’s headache. Often they are not of any clinical significance to the patient’s headaches or relevant clinically and can worry the patient, or require serial imaging. False positive studies include normal anatomic variants, transverse sinus asymmetry, non-specific white matter lesions, developmental venous anomaly, lipoma, prominent perivascular spaces (Virchow-Robin spaces), cysts, arachnoid granulations, small meningioma, or pituitary adenomas (12). They may lead to

further investigations with a lumbar puncture and its associated risks. Other risks to over imaging include false reassurance from an inadequate study, the rare risk of an allergic reaction to iodine contrast media with CT scanning, radiation from CT scans, and the risk of over-sedation in claustrophobic patients having MRI scans.

Older studies have looked at the cost-effectiveness of completing brain imaging in headache patients. In one study, 592 neurologically intact patients were examined between 1990 and 1993 for the complaint of headache. No patient was found to have serious intracranial pathology detected by CT scan (24). The societal cost implications are significant.

CONCLUSION

When to order neuroimaging can be a challenging decision faced by the clinician taking care of a patient with headaches. It is further complicated by incurred costs to the health care system and the potential medical-legal consequences. There are no available studies that allow for definitive recommendations on neuroimaging in headache patients. We do however have reasonable evidence-based studies and prevalence estimates, for example in patients with migraine and a normal neurological examination and significant intracranial pathology. We created a framework to help the clinician with an organized approach to neuroimaging in headache patients, and can be tailored on a case-by-case basis.

AUTHOR CONTRIBUTIONS

AM conceived of manuscript, involved in writing, and editing the manuscript. WK involved in writing and editing the manuscript.

REFERENCES

- Rasmussen BK, Jensen R, Schroll M, Olesen J. Epidemiology of headache in a general population—a prevalence study. *J Clin Epidemiol.* (1991) 44:1147–57. doi: 10.1016/0895-4356(91)90147-2
- Dodick DW. Migraine. *Lancet.* (2018) 391:1315–30. doi: 10.1016/S0140-6736(18)30478-1
- Headache Classification Committee of the International Headache Society. The International Classification of Headache Disorders, 3rd edition (beta version). *Cephalalgia.* (2013) 33:629–808. doi: 10.1177/0333102413485658
- Frishberg BM, Rosenberg JH, Matchar, DB, McCrory DC, Pietrzak MP, Rozen TD, et al. Evidence-based guidelines in the primary care setting: neuroimaging in patients with nonacute headache. *Am Acad Neurol.* (2000).
- Report of the Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: the utility of neuroimaging in the evaluation of headache in patients with normal neurologic examinations (summary statement). *Neurology.* (1994) 44:1353–4. doi: 10.1212/WNL.44.7.1353
- Evans RW, RT, Mechtler LL. Chapter 5: Neuroimaging and other diagnostic testing in headache. In: Silberstein SD, Lipton RB, Dodick DW, editors. *Wolff’s Headache and Other Head Pain*, 8th ed. New York, NY: Oxford University Press (2007).
- Olesen J, Friberg L, Olsen TS, Andersen AR, Lassen NA, Hansen PE, et al. Ischaemia-induced (symptomatic) migraine attacks may be more frequent than migraine-induced ischaemic insults. *Brain.* (1993) 116(Pt 1):187–202. doi: 10.1093/brain/116.1.187
- Shams PN, Plant GT. Migraine-like visual aura due to focal cerebral lesions: case series and review. *Surv Ophthalmol.* (2011) 56:135–61. doi: 10.1016/j.survophthal.2010.07.005
- Schwedt TJ. Chronic migraine. *BMJ.* (2014) 348:g1416. doi: 10.1136/bmj.g1416
- Dumas MD, Pexman JH, Kreeft JH. Computed tomography evaluation of patients with chronic headache. *CMAJ.* (1994) 151:1447–52.
- Dodick DW. Diagnosing headache: clinical clues and clinical rules. *Adv Stud Med.* (2003) 3:87–92. Available online at: [http://www.jhasim.com/files/articlefiles/pdf/journal_p87\(V3-2\)AmbulatoryM.pdf](http://www.jhasim.com/files/articlefiles/pdf/journal_p87(V3-2)AmbulatoryM.pdf)
- Mechtler LL. Neuroimaging of headaches. *Continuum.* (2008) 14:94–117. doi: 10.1212/01.CON.0000333202.83097.bc
- Schwedt TJ. Thunderclap headache. *Continuum.* (2015) 21:1058–71. doi: 10.1212/CON.0000000000000201
- Evans RW. Diagnostic testing for the evaluation of headaches. *Neurol Clin.* (1996) 14:1–26. doi: 10.1016/S0733-8619(05)70240-1
- Saposnik G, Barinagarrementeria F, Brown RD Jr, Bushnell CD, Cucchiara B, Cushman M, et al. Diagnosis and management of cerebral venous thrombosis: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* (2011) 42:1158–92. doi: 10.1161/STR.0b013e31820a8364
- Wall M, Kupersmith MJ, Kiebertz KD, Corbett JJ, Feldon SE, Friedman DI, et al. The idiopathic intracranial hypertension treatment trial: clinical profile at baseline. *JAMA Neurol.* (2014) 71:693–701. doi: 10.1001/jamaneurol.2014.133

17. Silbergleit R, Junck L, Gebarski SS, Hatfield MK. Idiopathic intracranial hypertension (pseudotumor cerebri): MR imaging. *Radiology*. (1989) 170 (1 Pt 1):207–9. doi: 10.1148/radiology.170.1.2909098
18. Gonzalez-Gay MA, Barros S, Lopez-Diaz MJ, Garcia-Porrúa C, Sanchez-Andrade A, Llorca J. Giant cell arteritis: disease patterns of clinical presentation in a series of 240 patients. *Medicine*. (2005) 84:269–76. doi: 10.1097/01.md.0000180042.42156.d1
19. Salvarani C, Hunder GG. Giant cell arteritis with low erythrocyte sedimentation rate: frequency of occurrence in a population-based study. *Arthritis Rheum*. (2001) 45:140–5. doi: 10.1002/1529-0131(200104)45:2<140::AID-ANR166>3.0.CO;2-2
20. Bley TA, Wieben O, Uhl M, Thiel J, Schmidt D, Langer M. High-resolution MRI in giant cell arteritis: imaging of the wall of the superficial temporal artery. *Am J Roentgenol*. (2005) 184:283–7. doi: 10.2214/ajr.184.1.01840283
21. Goadsby PJ. Trigeminal autonomic cephalalgias. *Continuum*. (2012) 18:883–95. doi: 10.1212/01.CON.0000418649.54902.0b
22. Gladstone J. From psychoneurosis to ICHD-2: an overview of the state of the art in post-traumatic headache. *Headache*. (2009) 49:1097–111. doi: 10.1111/j.1526-4610.2009.01461.x
23. Stiell IG, Wells GA, Vandemheen K, Clement C, Lesiuk H, Laupacis A, et al. The Canadian CT Head Rule for patients with minor head injury. *Lancet*. (2001) 357:1391–6. doi: 10.1016/S0140-6736(00)04561-X
24. Akpek S, Arac M, Atilla S, Onal B, Yücel C, Isik S. Cost-effectiveness of computed tomography in the evaluation of patients with headache. *Headache*. (1995) 35:228–30. doi: 10.1111/j.1526-4610.1995.hed3504228.x

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Understanding Health Information Technologies as Complex Interventions With the Need for Thorough Implementation and Monitoring to Sustain Patient Safety

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INTRODUCTION

As stated by the Institute of Medicine: “It is widely believed that health IT, when designed, implemented, and used appropriately, can be a positive enabler to transform the way care is delivered. Designed and applied inappropriately, health IT can add an additional layer of complexity to the already complex delivery of health care, which can lead to unintended adverse consequences, for example dosing errors, failure to detect fatal illnesses, and delayed treatment due to poor human–computer interactions or loss of data” (Institute of Medicine, 2012). In fact, health information technologies (HIT) have the potential to increase the performance of delivered services, increase health care quality, save costs and involve patients as effective partners of their own health care. One recent example that aims at providing such a technology is EHDViz, a clinical dashboard development using open-source technology integrating high-frequency health and wellness data streams using interactive and real-time data visualization and analytics modalities (Badgeley et al., 2016). By providing such collaborative data visualizations, wellness trend predictions, risk estimation, proactive activity status monitoring, and knowledge of complex disease indicators, EHDViz proved to be an essential prototype of implementing data-driven precision medicine to improve the quality of affordable health care delivery (Badgeley et al., 2016).

However, thorough implementation and monitoring of HIT that have proven effective into regular health care delivery is a central concern of patient safety research. If not implemented and monitored correctly, HIT have the potential to pose a severe threat to the patient’s health with a chance for lethal consequences due to implementation failure. Implementation failure is defined as failure to deliver a program as intended, which can result in failure to achieve the intended intervention effects or even adverse intervention effects (e.g., due to lack of acceptance) (Campbell et al., 2000; Rychetnik et al., 2002; Craig et al., 2008; Katz et al., 2013). Besides concrete harm for the patient due to implementation failure, additional risks are frustration and demoralization of staff as well as time loss which impede team performance in the delivery of care and, as a result, can also impact successful implementation (Ash et al., 2004; Harrison et al., 2007; Friedberg et al., 2014).

Though studies predominantly report positive consequences on patient safety parameters when using HIT (e.g., reduction of adverse events), a few studies also report on negative consequences (e.g., increase in mortality due to adverse events) which could have been avoided with thorough implementation and monitoring resulting in lives saved (Han et al., 2005; Brenner et al., 2016).

Ongoing digital transformation in the health care system (e.g., machine learning, big data) further highlights the importance to incorporate HIT thoroughly into settings and routines. A recent publication by Shameer et al. (2017) highlighted the benefits of translational, integrative bioinformatics as a driver for data-driven precision medicine and wellness care, but also mention the need for a "... seamless integration of data from clinical evaluations and biomedical investigations with genomics and other physiological profiling to characterize an individual patient's disease progression. Implementing precision medicine practices in clinical settings requires coordinated efforts to integrate data from both healthy and disease states in individuals." The authors propose the consolidated individualome data model which integrates environmental, person health related, and clinical data repositories and see electronic model records as a potential vehicle to centralize biomedical and health care data via real-time data streams (Shameer et al., 2017).

HEALTH INFORMATION TECHNOLOGIES ARE COMPLEX INTERVENTIONS

However, implementing and monitoring HIT while also considering patient safety as a central aim of digital transformation in health care is often easier said than done. By nature, HIT follow the principle rules of complex interventions which have an impact on several parts of organizational and team structures ranging from IT infrastructures to the point of care. As change agents, HIT affect health care delivery in predictable (e.g., reorganization of processes) and unpredictable ways (e.g., interrupt care delivery) (Drummond et al., 2009).

They do so by covering several dimensions of complexity: (1) Number of and interactions between components; (2) Number and difficulty of behaviors required by those delivering or receiving the intervention; (3) Number of groups or organizational levels targeted by the intervention; (4) Number and variability of outcomes; (5) Degree of flexibility or tailoring of the intervention permitted (Rychetnik et al., 2002). Therefore, complex interventions not only call for thorough implementation, but also evaluation methods to display and understand if and how different parts of complex interventions work in different contexts, and how these parts might be improved to facilitate overall success of the implementation of HIT and their effectiveness. As a result, complex interventions may work best if tailored to local circumstances rather than being completely standardized. According to Craig et al. (2008) it is best practice to develop complex interventions systematically by using the best available evidence and theory, followed by a series of pilot studies to target key uncertainties in the design, an explorative and a definitive evaluation. The evaluations' results are to be

disseminated as widely and persuasive as possible, with additional research to assist and monitor the process of implementation (Craig et al., 2008).

IMPLEMENTING COMPLEX HEALTH INFORMATION TECHNOLOGIES IN HIGH RELIABILITY HEALTH CARE ORGANIZATIONS

As health care organizations can be described as high reliability organizations (HRO) special emphasize needs to be put on the implementation of complex interventions to avoid implementation failure and potential harm to the patient. HROs in health care can be described by the following characteristics: (1) Preoccupation with failure; (2) Reluctance to simplify; (3) Sensitivity to operations; (4) Deference of expertise; (5) Commitment to resilience. According to the Agency for Healthcare Research and Quality, "the principles of high reliability go beyond standardization; high reliability is better described as a condition of persistent mindfulness within an organization. High reliability organizations cultivate resilience by relentlessly prioritizing safety over other performance pressures" (Agency for Healthcare Research and Quality, 2012).

To ensure quality and increase effectiveness of health care in HROs, implementation science provides the necessary repository of ideas and instruments to facility implementation and monitoring of HIT. Implementation science is defined as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services" (Eccles and Mittman, 2006). Therefore, increasing patient safety by improving quality and effectiveness of delivered health care go hand in hand with a major goal of implementation science. One of such instruments is the Consolidated Framework for Implementation Research (CFIR) as a pragmatic meta-theoretical framework (Damschroder et al., 2009). The CFIR represents the synthesis of 19 theories associated with implementation science to summarize potential barriers and facilitators of implementation, and to ensure consistent use of constructs across studies and support their comparability. These constructs are broadly subsumed under five domains: (1) Intervention characteristics; (2) Outer setting; (3) Inner setting; (4) Characteristics of individuals; (5) Process. These domains and their corresponding constructs (see **Table 1**) can complement the proposed key elements of the development and evaluation process of complex interventions by Craig et al. (2008) as displayed in the modified model for complex HIT interventions (see **Figure 1**) (Craig et al., 2008; Damschroder et al., 2009).

A PATIENT SAFETY EXAMPLE FOR IMPLEMENTATION FAILURE OF COMPLEX HEALTH INFORMATION TECHNOLOGIES

One particular example is a study by Han et al. (2005) which reported an unexpected increase in mortality after implementing a computerized physician order entry system (CPOE) in children

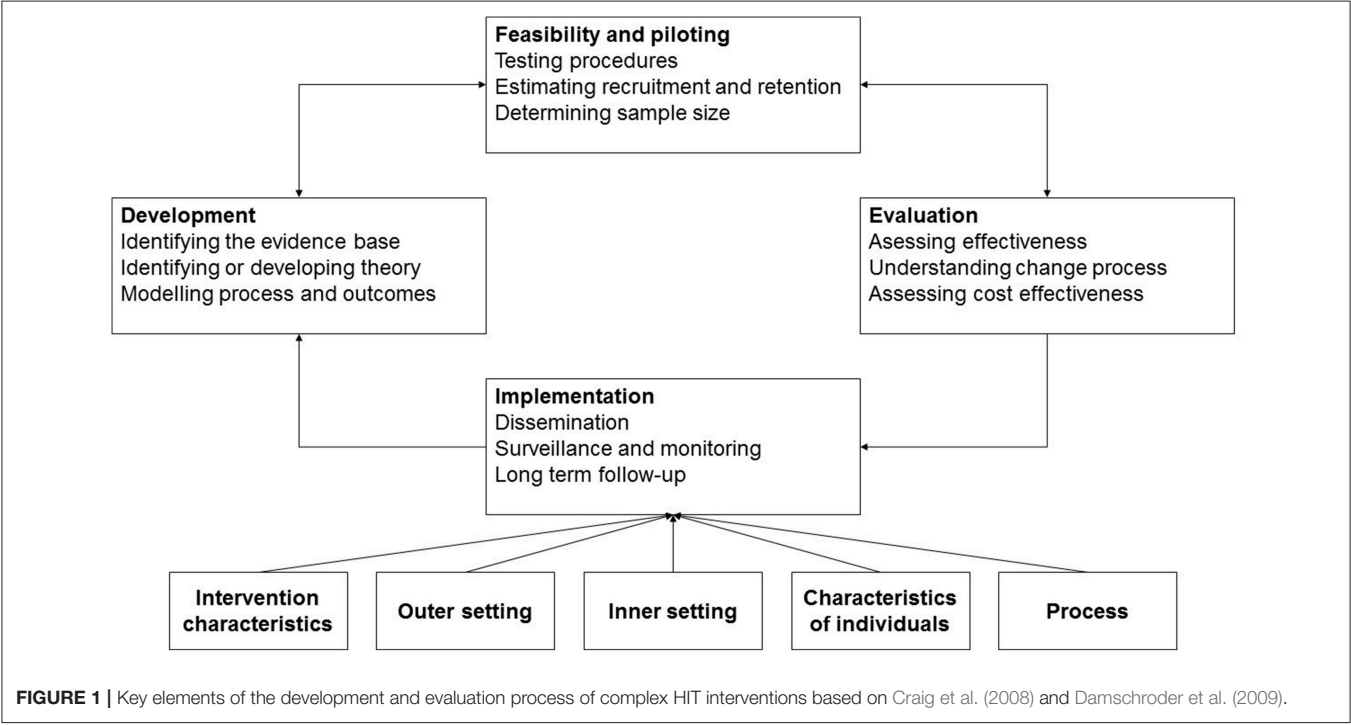
TABLE 1 | Domains, constructs, and their brief descriptions as displayed in Damschroder et al. (2009).

Domain	Construct	Brief description
Intervention characteristics	Intervention source	Perception of key stakeholders about whether the intervention is externally or internally developed.
	Evidence strength and quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
	Relative advantage	Stakeholders' perception of the advantage of implementing the intervention vs. an alternative solution.
	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs. Adaptability relies on a definition of the "core components" (the essential and indispensable elements of the intervention itself) vs. the "adaptable periphery" (adaptable elements, structures, and systems related to the intervention and organization into which it is being implemented) of the intervention.
Process	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
	Design quality and packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
	Cost	Costs of the intervention and costs associated with implementing that intervention, including investment, supply, and opportunity costs.
Outer setting	Patient needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
	Peer pressure	Mimetic or competitive pressure to implement an intervention, typically because most or other key peer or competing organizations have already implemented or in pursuit of a competitive edge.
	External policies and incentives	Broad constructs that encompass external strategies to spread interventions, including policy, and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.
Inner setting	Structural characteristics	The social architecture, age, maturity, and size of an organization. Social architecture describes how large numbers of people are clustered into smaller groups and differentiated, and how the independent actions of these differentiated groups are coordinated to produce a holistic product or service.
	Networks and communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
	Culture	Norms, values, and basic assumptions of a given organization. Most change efforts are targeted at visible, mostly objective, aspects of an organization that include work tasks, structures, and behaviors.
	Implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization (e.g., readiness for change).
Characteristics of individuals	Knowledge and beliefs about the intervention	Individuals' attitudes toward and value placed on the intervention, as well as familiarity with facts, truths, and principles related to the intervention.
	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
	Individual stage of change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
	Individual identification with organization	A broad construct related to how individuals perceive the organization and their relationship and degree of commitment to that organization.
	Other personal attributes	This is a broad construct to include other personal traits. Traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, innovativeness, tenure, and learning style have not received adequate attention by implementation researchers.
Process	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods.
	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.

(Continued)

TABLE 1 | Continued

Domain	Construct	Brief description
	Executing	Carrying out or accomplishing the implementation according to plan. Execution of an implementation plan may be organic with no obvious or formal planning, which makes execution difficult to assess.
	Reflecting and evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience. It is important to differentiate this processual construct from the Goals and Feedback construct under Inner Setting, described above. The focus here is specifically related to implementation efforts.



who are transported for specialized care to an intensive care unit (ICU). Though implementing the CPOE had the opposite intent (i.e., to reduce mortality), the authors report that observed mortality nearly doubled, increasing from 2.80 to 6.57% (Han et al., 2005). In non-survivors, the CPOE was used more often (48.0 vs. 27.4%; $P < 0.001$) and was an independent predictor of mortality in the final logistic regression model (OR = 3.28; 95% CI 1.94–5.55; $P < 0.001$). The authors describe in detail the restructured processes after the CPOE was implemented, highlighting diverse problems such as delay of care due to a complex ordering process which can only start when the patient is fully registered, communication bandwidth problems using wireless communication due to increased overall traffic in the hospital computer system, dislocation of medical personal as one physician was now needed to place orders for the first 15 to 60 min if a patient arrived in extremis, and the removal of a satellite medication dispenser for critical medication from the ICU as all medication now had to be located at the central pharmacy. Furthermore, medical staff at the ICU were logged

out when a pharmacist accessed the placed order for further processing, delaying additional order entries.

Though the displayed problems might not be exhaustive, they still underline the importance of thorough implementation of HIT as complex interventions. Referring to **Figure 1**, the authors reported on problems that emerged regarding intervention characteristics (e.g., external intervention source which was poorly adapted to the needs of the ICU and not tested on a small scale to identify potential problems, despite the potential to increase complexity of health care delivery in the ICU), the outer setting (i.e., not considering the patient needs for immediate care and treatment sufficiently), and process (poor planning of the implementation with no simulations or practice sessions for ICU staff or incremental implementation of parts of the intervention which might have provided important information at an early stage as well as a poor reflection and subsequent adaptation at an early stage of the implementation due to a lack of such “dry runs”). The majority of the reported problems might have transpired because the CPOE was externally developed, tested for

feasibility and evaluated, and was not well-implemented in the ICU, resulting in an increase in mortality. An implementation failure happened that would have likely cost lives.

CONCLUSION

Though this current opinion piece can be seen as a first step in understanding HIT as complex interventions, the example highlights that it can help guide their development, implementation, and evaluation. Special emphasize needs to be placed on the successful implementation of HIT to ensure high quality of care and patient safety with the aim of avoiding potential harm to patients. The proposed blended model introduced in this opinion piece can help to identify potential elements for implementation failure or to understand the adverse effects of HIT interventions by drawing on key elements of complex interventions, with a special emphasize on the implementation by including the CFIR.

Future studies that attend to the field of patient safety and HIT should (a) be aware of the complex nature of

HIT and consider this branch of research to enhance the understanding of working and non-working mechanisms in clinical settings by (b) drawing on insights from implementation science to avoid a failure of implementation with potential harm for patients. Additionally, relying on the CFIR and its' definition of domains and related constructs can also increase transparency regarding implementation effort and comparability with other studies.

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The author confirms being the sole contributor of this work and has approved it for publication.

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REFERENCES

- Agency for Healthcare Research and Quality (2017). *High Reliability*. Available online at: <https://psnet.ahrq.gov/primers/primer/31/high-reliability> (accessed July 19, 2018).
- Ash, J. S., Berg, M., and Coiera, E. (2004). Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *J. Am. Med. Inform. Assoc.* 11, 104–112. doi: 10.1197/jamia.M1471
- Badgeley, M. A., Shameer, K., Glicksberg, B. S., Tomlinson, M. S., Levin, M. A., McCormick, P. J., et al. (2016). EHDViz: clinical dashboard development using open-source technologies. *BMJ Open* 6:e010579. doi: 10.1136/bmjopen-2015-010579
- Brenner, S. K., Kaushal, R., Grinspan, Z., Joyce, C., Kim, I., Allard, R. J., et al. (2016). Effects of health information technology on patient outcomes: a systematic review. *J. Am. Med. Inform. Assoc.* 23, 1016–1036. doi: 10.1093/jamia/ocv138
- Campbell, M., Fritzpatrick, R., Haines, A., Kinmonth, A. L., Sandercock, P., Spiegelhalter, D., et al. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ* 321:694. doi: 10.1136/bmj.321.72.62.694
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., and Petticrew, M. (2008). *Developing and Evaluating Complex Interventions: The New Medical Research Council Guidance*. London: Medical Research Council. Available online at: <https://mrc.ukri.org/documents/pdf/complex-interventions-guidance> (accessed April 29, 2019).
- Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., and Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Imp. Sci.* 4:50. doi: 10.1186/1748-5908-4-50
- Drummond, W. H., Ferranti, J. M., Lehmann, C. U., and Lighter, D. E. (2009). "Complexity in healthcare information technology systems," in *Pediatric Informatics—Computer Applications in Child Health*, eds C. U. Lehmann, G. R. Kim, and K. B. Johnson (New York, NY: Springer), 83–117. doi: 10.1007/978-0-387-76446-7_8
- Eccles, M. P., and Mittman, B. S. (2006). Welcome to implementation science. *Imp. Sci.* 1:1. doi: 10.1186/1748-5908-1-1
- Friedberg, M. W., Chen, P. G., Van Busum, K. R., Aunon, F., Pham, C., Caloyer, J., et al. (2014). *Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy*. Santa Monica, CA: RAND Corporation. Available online at: https://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR439/RAND_RR439.pdf (accessed April 29, 2019).
- Han, Y. Y., Carcillo, J. A., Venkataraman, S. T., Clark, R. S., Watson, R. S., Nguyen, T. C., et al. (2005). Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. *Pediatrics* 116, 1506–1512. doi: 10.1542/peds.2005-1287
- Harrison, M. I., Koppel, R., and Bar-Lev, S. (2007). Unintended consequences of information technologies in health care—an interactive sociotechnical analysis. *J. Am. Med. Inform. Assoc.* 14, 542–549. doi: 10.1197/jamia.M2384
- Institute of Medicine (2012). *Health IT and Patient Safety. Building Safer Systems for Better Care*. Washington, DC: National Academies Press.
- Katz, J., Wandersman, A., Goodman, R. M., Griffin, S., Wilson, D. K., and Schillaci, M. (2013). Updating the FORECAST formative evaluation approach and some implications for ameliorating theory failure, implementation failure, and evaluation failure. *Eval. Program. Plann.* 39, 42–50. doi: 10.1016/j.evalprogplan.2013.03.001
- Rychetnik, L., Frommer, M., Hawe, P., and Shiell, A. (2002). Criteria for evaluating evidence on public health interventions. *J. Epidemiol. Commun. Health* 56, 119–127. doi: 10.1136/jech.56.2.119
- Shameer, K., Badgeley, M. A., Miotto, R., Glicksberg, B. S., Morgan, J. W., and Dudley, J. T. (2017). Translational bioinformatics in the era of real-time biomedical, health care and wellness data streams. *Brief. Bioinform.* 18, 105–124. doi: 10.1093/bib/bbv118

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Screening for Multiple Types of Family Violence: Development and Validation of the Family Polyvictimization Screen

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Objective: Different types of violence tend to co-occur within a family where the members often share common family characteristics, a situation described as family polyvictimization. In response to the lack of a validated screening tool, this study developed and validated the Family Polyvictimization Screen (FPS), the first brief screening tool applicable to members of the same family with up to three generations.

Methods: The FPS was designed to screen family polyvictimization by assessing and capturing different types of violence, including child abuse and neglect (CAN), intimate partner violence (IPV), and elder abuse. The FPS was compared with the Criterion Standard scales. It is suitable for use as a self-report for individual family members for specific violence or as a proxy report for an adult family member to serve as informant. In this study, a community sample of 445 households was recruited from Hong Kong ($n = 250$) and Shanghai ($n = 195$). One adult parent from each three-generation family was selected as the informant to report all family polyvictimization experiences in the preceding year.

Results: Moderate to high agreement (79.1–99.8%) was found between the FPS and the standard measurements, such as the revised Conflict Tactics Scales (CTS2) and the Conflict Tactics Scales: Parent-Child Version (CTSPC). Exceptions appeared in regard to physical assault on elders due to the rarity of reported cases. The specificity was high, while the sensitivity estimates appeared low, especially for the more sensitive sexual abuse cases.

Conclusion: The validated FPS demonstrated its potential utility as a brief tool for screening family polyvictimization in clinical settings with substantial agreement and satisfactory accuracy in the Chinese population.

Keywords: family polyvictimization, screen, intimate partner violence, child abuse and neglect, elder abuse, validation

INTRODUCTION

Family polyvictimization is defined as the co-occurrence of child abuse and neglect (CAN), parental intimate partner violence (IPV), and elder abuse against different members in the same family (1). In past decades, studies have examined an array of different types of violence toward different family members either by focusing on one specific type or by covering various types and intensities

of violence (2). Recent studies have confirmed that the effects of two or more types of violence victimization experiences could lead to more severe and less reversible impacts on the victims (1, 3). A recent study revealed that ~2.5% of families in China have experienced multiple types of violence (1), suggesting that family polyvictimization is not a rare phenomenon and highlighting the need for more research attention to be focused on this concept.

Currently, different types of family violence are often captured individually using different tools for specific targets or settings. For example, the common tools available for studying IPV include the Index of Spouse Abuse, the Danger Assessment Screen, and the revised Conflict Tactics Scales (CTS2). These tools have been widely used and modified to fit a wide range of practical uses or to address various research objectives and designs (4, 5). The usefulness of these measures has been promising; however, some of them comprise numerous detailed items that require a relatively long time to complete, thereby limiting their application as a quick screening tool for use in clinical settings. Some existing scales have been employed as Criterion Standard for screening or identifying IPV in clinical settings. For instance, the Chinese Abuse Assessment Screen (AAS) and the Hurt, Insult, Threaten, and Scream Scale (HITS) are brief assessments composed of three to four questions that have been proved reliable (6, 7). Yet, these brief screening tools have also been criticized as being unable to capture sufficient information; for example, the AAS focuses only on female victims, and it has been shown to be insensitive in capturing minor episodes of IPV (8). With the existing screening and assessment tools for IPV, striking a balance between speediness and thoroughness could be a challenging task.

Apart from the difficulty in balancing measuring speed and thoroughness, current screening or assessment tools may also face other types of challenges. For example, when assessing elder abuse, a relatively new issue in the field, researchers may face limitations in scope among the existing tools (9). The unique concerns of elderly people with regard to the administration of assessments have been recognized: for example, memory difficulties and visual impairments (10). To overcome these challenges, studies on elder abuse usually adopt structured face-to-face interviews with the elderly or their caregivers (11). However, little progress has been made in validating measures of sexual abuse and neglect toward the elderly (12), resulting in researchers experiencing difficulties in estimating reliable figures or conducting relevant studies on these issues.

Similar challenges appear in assessments on violence among the young population, who could be easily affected by people from a wide range of settings, such as their nuclear family, extended family, school, and neighborhood. Currently, some scales on CAN have been adapted from existing assessment tools capturing other types of family violence among the adult population [e.g., the Conflict Tactics Scales: Parent-Child version (CTSPC) (13)]. As the roles and impacts of parents and other family members are prominent during early childhood, assessments of CAN often include items to capture children's experience of witnessing parental conflict and sibling violence. For instance, the Juvenile Victimization Questionnaire (JVQ) provides a comprehensive assessment of conventional

crime, child maltreatment, peer and sibling victimization, sexual victimization, and witnessing/indirect victimization (14). This highlights the importance of including items that can thoroughly capture all aspects of violence experiences across victims at different stages of development.

Recent research on the assessment of violence has focused on the measurement of different subtypes of violent behaviors that constitute polyvictimization (15). As outlined by the Centers for Disease Control and Prevention, the four major subtypes of victimization are physical violence, sexual violence, stalking, and psychological aggression (16). Studies have noted that the assessment of child exposure to IPV is often limited to physical violence between parents instead of including other types, such as psychological aggression (17). Failure to assess or the tendency to underreport sexual abuse appears to be common in current research findings, and this may lead to its prevalence being underestimated when making decisions on future actions (18). The evidence above reinforces the critical importance of comprehensive screening approaches for polyvictimization to detect polyvictims in advancing our understanding of the co-occurrence of family violence and identifying directions for its prevention (19).

In response to the lack of a validated screening tool, this study developed and validated the Family Polyvictimization Screen (FPS), the first brief screening tool to assess CAN, IPV, and elder abuse within a family, covering different types of violence across all family members up to three generations (i.e., grandparents, parents, and children).

METHODS

Sample and Procedures

We followed the research design and analyses employed in the previous validation of the Chinese Abuse Assessment Screen (AAS) (7). The purpose of the study is not to report on prevalence or correlates of family polyvictimization. We employed a convenience sample of households from various communities in Shanghai and Hong Kong. The two chosen cities are relatively developed compared to other cities in China. Households in central and suburban districts were selected and included to maximize the diversity of participants with different socioeconomic characteristics. Eligible households were those with at least one child aged 18 years or younger living together with their parents and/or grandparents. One parent or caregiver from each of the sampled families was randomly selected as the informant to report the victimization experiences of all family members. If more than one child or one grandparent were eligible, the one with the most recent birthday was selected as the target of the study. No identifying information of the participants was recorded, and anonymity, privacy, and the right to refuse were ensured in all procedures.

Participation in the study was voluntary, and each participant gave their informed consent prior to the interviews. Informants were given the choice of completing either a printed or computer-assisted questionnaire, and the completed questionnaires were collected by trained interviewers. Confidentiality was guaranteed by assigning a sample code to each completed

questionnaire instead of using the respondent's name. The printed questionnaires and signed consent forms were kept in a locked cabinet that was only accessible to the principal investigator. Respondents using the computer-assisted questionnaire were only identified by code numbers so that under no circumstances could the information be revealed outside of the research team. All the interviewers received intensive training on the procedure and ethical issues related to working with participants who report violence. All participants were given an information card with details about social services related to violence prevention to enable them to seek help whenever necessary. The Human Subjects Ethics Subcommittee of the authors' affiliated university provided ethics approval for the entire study.

Measures

The Family Polyvictimization Screen

Items developed for the FPS were constructed by a group of medical and social sciences professionals led by the first author. The items were grouped into four modules: (a) IPV victimization, (b) IPV perpetration, (c) CAN, and (d) elder abuse. The 11 items of the four modules of the FPS and examples of the violent acts reported by respondents as a reference are listed in the **Appendix**. The IPV victimization and IPV perpetration modules both consisted of three items covering psychological aggression, physical assault, and sexual abuse. The CAN module comprised three items assessing psychological aggression, physical assault, and neglect of children, while the elder abuse module was composed of two items, namely, psychological aggression, and physical assault. We considered including sexual abuse, elder neglect, and financial exploitation. However, due to the lack of existing assessment tools for other forms of victimization, including elder neglect, elder sexual abuse, and financial exploitation, we could not validate those items using Criterion Standard in this study. Thus, we tested two items at this stage.

All 11 items were dichotomous questions. Sample items include "Have you ever experienced physical victimization?" and "Has your child ever been neglected?" Each question was accompanied with examples of the relevant violent behaviors to help the respondents assess and estimate whether they had witnessed or experienced such violence before. For example, psychological aggression could be the behaviors of a family member who "yells at you, is hypercritical of you, shames you, ridicules you, monitors you, isolates you from friends/family, threatens to hit you or throw something at you, accuses you, or destroys something that belongs to you." These examples were referenced to the items listed in the Criterion Standard scales.

When respondents provided a "yes" response to a question, they were asked to indicate the identity of the perpetrator and the time frame of the victimization experiences. For the IPV victimization and IPV perpetration modules, the perpetrator(s) could be the respondents themselves, their partner, their father, their mother, their father-in-law, their mother-in-law, their child, or other relatives living in the household. For the CAN module, the possible perpetrator(s) were the same as those in the IPV modules, except for the "child" option, which was replaced by

"sibling(s)." For elder abuse, possible perpetrator(s) covered the respondents themselves, their partner, the partner of the elderly victim, their child, and other relatives living together in the household. The participants were asked to report whether the victimization "happened in the preceding year" or "happened before the preceding year."

"Criterion Standard" Scales for Validation

The Criterion Standard scales include a series of questions to identify specific types of victimization for both screening in clinical settings and identifying victims in research which are expected to detect true positive cases or dismiss negative cases (7).

IPV Perpetration and Victimization

The revised CTS2 was used as the standard to validate the IPV victimization and perpetration modules (20). The CTS2 questionnaire is commonly adopted around the globe for measuring the prevalence, chronicity, and severity of spousal conflicts. This study adopted all eight questions from the Psychological Aggression subscale, 12 questions from the Physical Assault subscale, and six questions from the Injury subscale, as well as seven questions from the Sexual Coercion subscale for comparison.

Child Abuse and Neglect

In the case of CAN, we combined items from the CTSPC (13) and the JVQ (14), with the justification that neither scale on its own covered all the modules that we developed for validation. The psychological aggression and physical assault parts of the CAN module were compared with questions from the CTSPC, including the five questions from the Psychological Aggression subscale and 13 questions from the Physical Assault subscale. On the other hand, items related to child neglect were validated by those extracted from the JVQ, including five questions from the Supplemental Neglect subscale.

Elder Abuse and Neglect

The modified Conflict Tactics Scales (CTS) were used to validate the elder abuse module (20). This study employed 10 questions of the Psychological Aggression subscale and 13 questions of the Physical Assault subscale of the CTS.

For all the questions on victimization, the respondents were asked to indicate the time frame of the experiences: "happened in the preceding year," "happened before the preceding year," or "never happened." When they provided a "yes" response to any of the victimization items, they were then asked to indicate specifically the perpetrator who conducted the specific violent behavior against the victim. The perpetrator options were the same as those in the items developed for the FPS.

Demographic Characteristics

A series of questions was used to collect information on the demographic, socioeconomic, and family characteristics of the respondents and their family members. Participants were asked to report family members' gender, age, residence status (i.e., whether they were living together in the same household), highest education level, employment status, marital status, and

family income and whether they were receiving any social security assistance.

Statistical Analyses

Demographic, socioeconomic, and family factors were summarized in descriptive statistics. Between-group comparisons were conducted to ensure there was no significant difference between the subsamples recruited from Hong Kong and Shanghai. The levels of agreement of the FPS items and those from the Criterion Standard were compared and analyzed using kappa coefficients. To assess the diagnostic accuracy and utility of using the FPS for screening various types of victimization, the sensitivity (SE), specificity (SP), positive and negative predictive values (PPV & NPV), and the positive and negative likelihood ratios (PLR & NLR) were computed using the related Criterion Standard (21). If the sum of sensitivity and specificity was >1 , the FPS would be considered as a useful tool (22). In this study, blank answers were treated as missing values in the analyses. All estimates were accompanied by an exact 95% confidence interval, a p -value <0.05 was considered statistically significant, and all statistical analyses were performed in SPSS version 23.0.

RESULTS

Data from 445 parents and their families, 250 from Hong Kong, and 195 from Shanghai, were analyzed in this study, with response rates of 77.8 and 86.2%, respectively. The non-responses were mainly non-contacts, and $<5\%$ were refusals. No participants dropped out after agreeing to take part in the study. In the sample, 48.0% of the Hong Kong families had one child in the family and 44.8% had two, while the majority of the Shanghai families (83.1%) had only one child. The mean ages of parents were similar in the subsamples from the two cities, with the fathers having a mean age of around 40.0 years ($SD = 9.52$) and the mothers a mean age of around 38.5 years ($SD = 7.17$). The mean age of the selected children was 9.0 years ($SD = 2.91$), while the mean ages of the grandparents were 70 (Hong Kong) and 61 (Shanghai). Most of the parents were married or cohabiting with their current partner (95.5%) and lived together with their children (97.3%). Approximately 11.2% of the grandparents from Hong Kong and 26.5% of the grandparents from Shanghai lived with parents and children in the same household. The results showed no significant difference in demographic background between the subsamples from the two cities.

Table 1 shows the percentages of agreement and the kappa coefficients between the items from the FPS and the items from the selected Criterion Standard. Overall, moderate agreements were found between the FPS items and those from the standards, although the kappa coefficients ranged from fair (around 0.20) to substantial (over 0.70). For elderly physical assault, however, the kappa coefficients were not available, except for assault by elderly partner. Comparisons were not possible due to the limited number of cases ($n \leq 1$) reported by the respondents.

Table 2 shows the accuracy of the items on various types of victimization in the preceding year. The sensitivity estimates were generally satisfactory, ranging from 54.5 to 81.0%, except for

TABLE 1 | Agreement between the family polyvictimization scale and the criterion standards ($N = 445$).

Type of abuse	Agreement % (95% CI)	Kappa coefficient	p-value
IPV VICTIMIZATION (RESPONDENT)			
Psychological aggression	87.0 (83.5–90.0)	0.737	<0.001
Physical assault/Injury	91.2 (88.2–93.7)	0.565	<0.001
Sexual abuse	97.8 (95.9–98.9)	0.490	<0.001
IPV VICTIMIZATION (PARTNER)			
Psychological aggression	87.0 (83.5–90.0)	0.729	<0.001
Physical assault/Injury	90.8 (87.7–93.3)	0.404	<0.001
Sexual abuse	97.8 (95.9–98.9)	0.158	<0.001
CHILD ABUSE–PSYCHOLOGICAL AGGRESSION			
By respondent	82.2 (78.4–85.7)	0.643	<0.001
By partner	79.1 (75.0–82.8)	0.579	<0.001
By grandparents	89.0 (85.7–91.7)	0.593	<0.001
By brothers and sisters	96.2 (94.0–97.8)	0.544	<0.001
CHILD ABUSE–PHYSICAL ABUSE			
By respondent	82.0 (78.1–85.5)	0.519	<0.001
By partner	82.7 (78.9–86.1)	0.382	<0.001
By grandparents	94.2 (91.6–96.2)	0.384	<0.001
By brothers and sisters	96.6 (94.5–98.1)	0.269	<0.001
CHILD ABUSE–NEGLECT			
By respondent	92.6 (89.7–94.8)	0.202	<0.001
By partner	95.3 (92.9–97.1)	0.378	<0.001
By grandparents	96.4 (94.2–97.9)	0.410	<0.001
ELDERLY ABUSE–PSYCHOLOGICAL AGGRESSION			
By respondent	93.7 (91.0–95.8)	0.529	<0.001
By partner	93.9 (91.3–96.0)	0.440	<0.001
By grandparents	91.7 (88.7–94.1)	0.368	<0.001
By respondents' children	96.2 (94.0–97.8)	0.302	<0.001
ELDERLY ABUSE–PHYSICAL ASSAULT			
By respondent	99.3 (98.0–99.9)	–	–
By partner	99.8 (98.8–100.0)	–	–
By grandparents	99.3 (98.0–99.9)	0.397	<0.001
BY respondents' children	99.8 (98.8–100.0)	–	–

IPV, intimate partner violence.

child neglect, the sensitivity estimate for which was only 16.1%. The specificity estimates ranged from 83.8 to 99.8%.

DISCUSSION

The findings from this study provide preliminary supportive evidence for the effectiveness of the 11-item FPS as a brief screening tool to identify cases involving family polyvictimization in the Chinese population. Moderate

TABLE 2 | Accuracy of the family polyvictimization scale for screening preceding-year family victimization ($N = 445$).

Polyvictimization scale	Gold standards							
	+ + a − c	− b d	Se % (95% CI)	Sp % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	PLR (95% CI)	NLR (95% CI)
IPV VICTIMIZATION (RESPONDENT)								
Psychological aggression	166 46	12 221	78.3 (72.8–83.9)	94.8 (92.0–97.7)	93.3 (89.6–96.9)	82.8 (78.2–87.3)	15.2 (8.7–26.5)	0.23 (0.18–0.30)
Physical assault/Injury	31 25	14 375	55.4 (42.3–68.4)	96.4 (94.6–98.3)	68.9 (55.4–82.4)	93.8 (91.4–96.1)	15.4 (8.7–27.1)	0.46 (0.35–0.62)
Sexual abuse	5 9	1 430	35.7 (10.6–60.8)	99.8 (99.3–100.2)	83.3 (53.5–113.2)	97.9 (96.6–99.3)	–	0.64 (0.44–0.95)
IPV VICTIMIZATION (PARTNER)								
Psychological aggression	147 44	14 240	77.0 (71.0–82.9)	94.5 (91.7–97.3)	91.3 (87.0–95.7)	84.5 (80.3–88.7)	14.0 (8.3–23.4)	0.24 (0.18–0.32)
Physical assault/Injury	17 25	16 387	40.5 (25.6–55.3)	96.0 (94.1–97.9)	51.5 (34.5–68.6)	93.9 (91.6–96.2)	10.2 (5.6–18.7)	0.62 (0.48–0.80)
Sexual abuse	1 8	2 434	11.1 (0.0–31.6)	99.5 (98.9–100.2)	33.3 (0.0–86.7)	98.2 (96.9–99.4)	24.2 (2.4–243.5)	0.89 (0.71–1.13)
CHILD ABUSE-PSYCHOLOGICAL AGGRESSION								
By respondent	201 47	32 165	81.0 (76.2–85.9)	83.8 (78.6–88.9)	86.3 (81.8–90.7)	77.8 (72.2–83.4)	5.0 (3.6–6.9)	0.23 (0.17–0.30)
By partner	156 56	37 196	73.6 (67.7–79.5)	84.1 (79.4–88.8)	80.8 (75.3–86.4)	77.8 (72.6–82.9)	4.6 (3.4–6.3)	0.31 (0.25–0.40)
By grandparents	47 35	14 349	57.3 (46.6–68.0)	96.1 (94.2–98.1)	77.0 (66.5–87.6)	90.9 (88.0–93.8)	14.9 (8.6–25.7)	0.44 (0.35–0.57)
By brothers and sisters	11 7	10 417	61.1 (38.6–83.6)	97.7 (96.2–99.1)	52.4 (31.0–73.7)	98.3 (97.1–99.6)	26.1 (12.8–53.3)	0.40 (0.22–0.71)
CHILD ABUSE-PHYSICAL ABUSE								
By respondent	70 52	28 295	57.4 (48.6–66.2)	91.3 (88.3–94.4)	71.4 (62.5–80.4)	85.0 (81.3–88.8)	6.6 (4.5–9.7)	0.47 (0.38–0.58)
By partner	36 50	27 332	41.9 (31.4–52.3)	92.5 (89.8–95.2)	57.1 (44.9–69.4)	86.9 (83.5–90.3)	5.6 (3.6–8.6)	0.63 (0.52–0.75)
By grandparents	9 22	4 410	29.0 (13.1–45.0)	99.0 (98.1–100.0)	69.2 (44.1–94.3)	94.9 (92.8–97.0)	30.0 (9.8–92.1)	0.72 (0.57–0.90)
By brothers and sisters	3 5	10 427	37.5 (4.0–71.0)	97.7 (96.3–99.1)	23.1 (0.2–46.0)	98.8 (97.8–99.9)	16.4 (5.5–48.5)	0.64 (0.37–1.09)
CHILD ABUSE-NEGLECT								
By respondent	5 26	7 407	16.1 (3.2–29.1)	98.3 (97.1–99.6)	41.7 (13.8–69.6)	94.0 (91.8–96.2)	9.5 (3.2–28.3)	0.85 (0.73–1.0)
By partner	7 16	5 417	30.4 (11.6–49.2)	98.8 (97.8–99.8)	58.3 (30.4–86.2)	96.3 (94.5–98.1)	25.7 (8.8–74.8)	0.70 (0.54–0.92)
By grandparents	6 8	8 423	42.9 (16.9–68.8)	98.1 (96.9–99.4)	42.9 (16.9–68.8)	98.1 (96.9–99.4)	23.1 (9.2–57.6)	0.58 (0.37–0.92)
ELDERLY ABUSE-PSYCHOLOGICAL AGGRESSION								
By respondent	18 15	13 399	54.5 (37.6–71.5)	96.8 (95.2–98.5)	58.1 (40.7–75.4)	96.4 (94.6–98.2)	17.3 (9.3–32.1)	0.47 (0.32–0.68)
By partner	12 19	8 406	38.7 (21.6–55.9)	98.1 (96.7–99.4)	60.0 (38.5–81.5)	95.5 (93.6–97.5)	20.0 (8.9–45.3)	0.63 (0.47–0.83)
By grandparents	13 20	17 395	39.4 (22.7–56.1)	95.9 (94.0–97.8)	43.3 (25.6–61.1)	95.2 (93.1–97.2)	9.5 (5.1–17.9)	0.63 (0.48–0.83)
By respondents' children	4 5	12 424	44.4 (12.0–76.9)	97.2 (95.7–98.8)	25.0 (3.8–46.2)	98.8 (97.8–99.9)	16.1 (6.4–40.5)	0.57 (0.32–1.03)

(Continued)

TABLE 2 | Continued

Polyvictimization scale	Gold standards							
	+	−	Se % (95% CI)	Sp % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	PLR (95% CI)	NLR (95% CI)
	+ a	b						
	− c	d						
ELDERLY ABUSE-PHYSICAL ASSAULT								
By respondent	0	2	−	−	−	−	−	−
	1	442						
By partner	1	0	−	−	−	−	−	−
	1	443						
By grandparents	1	1	33.3 (0.0–86.7)	99.8 (99.3–100.2)	50.0 (0.0–119.3)	99.5 (98.9–100.2)	147.3 (11.8–1847.0)	0.67 (0.30–1.49)
	2	441						
By respondents’ children	1	0	−	−	−	−	−	−
	1	443						

CI, confidence interval; +, positive response; –, negative response; a, true positive; b, false negative; c, false positive; d, true negative; IPV, intimate partner violence; NLR, negative likelihood ratio; NPV, negative predictive values; PLR, positive likelihood ratio; PPV, positive predictive values; Se, sensitivity; Sp, specificity.

agreements were found between the FPS and the Criterion Standard. Concerning violent behaviors inflicted by the respondents themselves, the sensitivity estimates were generally satisfactory. From 54.5 to 81.0% cases were confirmed as positive by the Criterion Standard when the FPS reported positive. However, for some other types of violence, such as IPV sexual abuse and elderly abuse, the sensitivity estimates were around 30–40%, which were relatively low. Yet, all of the sensitivity estimates in this study were > “1–specificity,” reflecting that the FPS is an informative assessment tool (22). Specificity estimates indicated that when the response on the FPS was negative, it was likely that the response on the relevant standard assessments was also negative. The relatively satisfactory negative predictive values (77.8–99.5%) for the various forms of victimization suggested that among those who were screened negative by the FPS, the probability of victimization-free responses in the standards was substantially high. In contrast, the findings on the sensitivity estimates and the positive predictive values were mixed. The positive likelihood ratios provided further support for the usefulness of the FPS. In this study, most of the values were > 10, reflecting a high increase in the probability of having experienced the specific violence given a positive response to the FPS. The relatively lower sensitivity of the FPS for IPV sexual abuse, elderly abuse, and child neglect may have been caused by the lower prevalence rates of these types of violence in this sample. Thus, the number of abuse cases identified may not have been sufficient to compute for high sensitivity estimates. A larger sample will be required to further test the sensitivity of the FPS for IPV sexual abuse and elderly abuse.

There are limitations of the study's design that may be caused by underreporting. In this study, adult parents were recruited as informants to report the victimization experiences of their three-generation family, including grandparents, parents (respondents), and children. Adult parents were expected to be the most familiar with the situations and experiences of

other family members and thus the ones who could provide credible information about the details of the incidents and contexts of violence. In proxy reports, underreporting could be a concern, especially when the proxy is the perpetrator or when the proxy is not familiar with the reported target. The ideal arrangement is to involve all family members in reporting their own experience of victimization. However, this may involve other limitations: for example, interviewing children directly to gain information on retrospective traumatic experiences has been a controversial ethical topic in the field (23, 24), and some may argue that elderly people are basically less capable of responding to written questionnaires due to memory and visual impairments (10). Yet, in busy environments such as clinical settings, proxy reports on family polyvictimization by a single informant could be a possible solution. In fact, past studies have found moderate between-partner agreement on IPV perpetration and victimization and satisfactory parent-child agreement on minor child abuse such as corporal punishment (25–27), providing support for the use of proxy reports in the early-stage screening of family polyvictimization when individual self-reports are not feasible. The decision to invite parents to be informants might also be justified by the findings from past research suggesting that adult parents, as proxies, could provide generally adequate and comparable information to child self-reports about the experiences of children (1, 14). In view of the limitations that may be caused by engaging different family members in different cultures in reporting victimization, future studies may consider to test the FPS in different countries and to engage different informants to demonstrate the effectiveness and reliability.

Except in the case of assault by elder partner, accuracy estimates were not available in regard to physical aggression toward elderly people. The FPS item on psychological aggression demonstrated satisfactory accuracy, while the accuracy of the item on physical assault appeared somewhat lower. This provides

the literature with divergent evidence demonstrating that elder physical abuse can be more readily measured than the more subtle psychological form Schofield et al. (12, 28). A possible explanation for this is that respondents might not realize that the identification of elder physical assault should be determined by the act itself rather than by the injury sustained from the act, which leads to a negative response with regard to physical abuse if no injury was observed. Besides, elder neglect and elder financial exploitation have no standardized scales for validation. Little progress has been made in validating measures of these types of violence, although recent efforts have expanded the understanding of elder abuse by covering financial exploitation or elderly self-neglect (29). Further research is needed to meet this challenge and to better capture the less examined types of elder victimization. Moreover, studies have revealed that caregivers as proxy might report extremely low rates of the elder violence and tend to recognize only severe observable symptoms (30). It is plausible to include elderly informants to reflect a more sensitive and real picture of victimization experiences.

Implications

The development of the FPS has advanced the current screening assessments for violence by providing a brief tool covering several types of violence in the family for use in the Chinese context. This study demonstrated the FPS as a brief tool for use in detecting family polyvictimization. The development and validation of the FPS could be promising to facilitate future research on violence screening using a family-oriented approach, which in turn may promote proactive screening and better coordination of community responses for victims. It has been found that when one type of violence happens to a member of a family, the likelihood of revealing other types of violence to the same family member or to other family members will increase (1). Therefore, screening for family polyvictimization whenever one type of family violence is detected might be an effective way to detect and identify family polyvictimization early. A brief screening tool is key to extending current knowledge on family violence and the polyvictimization phenomenon (12).

To conclude, violent relationships often originate from a nuclear family and spill over into the extended family. The use of measures that assess only one or a few forms of victimization individually may impede our ability to understand some key aspects of family violence and polyvictimization, from identifying the potential polyvictims to examining the extent and comparing

the relative effects of different types of victimization. The validated FPS has demonstrated its potential utility as a holistic tool for screening family polyvictimization in clinical settings with substantial agreement and satisfactory accuracy in the Chinese population.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this manuscript will be made available by the authors, without undue reservation, to any qualified researcher.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University (Reference Number: HSEARS20180706002). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

KC conceptualized the study design, interpreted the data, and critically revised the manuscript. KC and QC analyzed the data and drafted the manuscript. MC, CL, and LY interpreted the data and critically revised the manuscript. All authors approved the final manuscript as submitted.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2019.00282/full#supplementary-material>

REFERENCES

- Chan KL. Family polyvictimization and elevated levels of addiction and psychopathology among parents in a Chinese household sample. *J Interpers Violence*. (2017) 32:2433–52. doi: 10.1177/0886260515592617
- Edleson JL, Shin N, Armendariz KK. Measuring children's exposure to domestic violence: the development and testing of the Child Exposure to Domestic Violence (CEDV) Scale. *Child Youth Serv Rev*. (2008) 30: 502–21. doi: 10.1016/j.childyouth.2007.11.006
- Finkelhor D, Turner H, Hamby SL, Ormrod R. *Polyvictimization: Children's Exposure to Multiple Types of Violence, Crime, and Abuse*. National Survey of Children's Exposure to Violence (2011). Available online at: <https://www.ncjrs.gov/pdffiles1/ojdp/235504.pdf> (accessed July 11, 2019).
- Leung WC, Kung F, Lam J, Leung TW, Ho PC. Domestic violence and postnatal depression in a Chinese community. *Int J Obstet Gynecol*. (2002) 79:159–66. doi: 10.1016/S0020-7292(02)00236-9
- Soeken KL, McFarlane J, Parker B, Lominack MC. The Abuse Assessment Screen: a clinical instrument to measure frequency, severity, and perpetrator of abuse against women. *Violence Against Women*. (1998) 10:195–203.
- Sherin KM, Sinacore JM, Li XQ, Zitter RE, Shakil A. HITS: a short domestic violence screening tool for use in a family practice setting. *Fam Med*. (1998) 30: 508–12.

7. Tiwari A, Fong DY, Chan KL, Leung WC, Parker B, Ho PC. Identifying intimate partner violence: comparing the Chinese abuse assessment screen with the Chinese revised Conflict Tactics Scales. *BJOG*. (2007) 114:1065–71. doi: 10.1111/j.1471-0528.2007.01441.x
8. Reichenheim ME, Moraes CL. Comparison between the abuse assessment screen and the revised Conflict Tactics Scales for measuring physical violence during pregnancy. *J Epidemiol Community Health*. (2004) 58:523–7. doi: 10.1136/jech.2003.011742
9. Abolfathi Momtaz Y, Hamid TA, Ibrahim R. Theories and measures of elder abuse. *Psychogeriatrics*. (2013) 13:182–8. doi: 10.1111/psyg.12009
10. Frank L, Flynn J, Rothman M. Use of a self-report constipation questionnaire with older adults in long-term care. *Gerontologist*. (2001) 41: 778–86. doi: 10.1093/geront/41.6.778
11. Fulmer T, Paveza G, Abraham I, Fairchild S. Elder neglect assessment in the emergency department. *J Emerg Nurs*. (2000) 26: 436–43. doi: 10.1067/men.2000.110621
12. Schofield MJ. Screening for elder abuse: tools and effectiveness. In: Dong X, editors. *Elder Abuse*. Cham:Springer (2017). p. 161–199. doi: 10.1007/978-3-319-47504-2_9
13. Straus MA, Hamby SL, Finkelhor D, Moore DW, Runyan D. Identification of child maltreatment with the Parent-Child Conflict Tactics Scales: development and psychometric data for a national sample of American parents. *Child Abuse Negl*. (1998) 22:249–70. doi: 10.1016/S0145-2134(97)00174-9
14. Finkelhor D, Ormrod RK, Turner HA, Hamby SL. Measuring polyvictimization using the Juvenile Victimization Questionnaire. *Child Abuse Negl*. (2005) 29:1297–312. doi: 10.1016/j.chiabu.2005.06.005
15. Jouriles EN, McDonald R, Vu NL, Sargent KS. Children's exposure to intimate partner violence: should sexual coercion be considered? *J Fam Psychol*. (2016) 30:503–8. doi: 10.1037/fam0000146
16. Breiding M, Basile K, Smith S, Black M, Mahendra R. *Intimate Partner Violence Surveillance: Uniform Definitions and Recommended Data Elements, Version 2.0*. Atlanta, GA: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (2015).
17. Vu NL, Jouriles EN, McDonald R, Rosenfield D. Children's exposure to intimate partner violence: a meta-analysis of longitudinal associations with child adjustment problems. *Clin Psycho Rev*. (2016) 46:25–33. doi: 10.1016/j.cpr.2016.04.003
18. Hamby S. Intimate partner and sexual violence research: scientific progress, scientific challenges, and gender. *Trauma Violence Abuse*. (2014) 15:149–58. doi: 10.1177/1524838014520723
19. Follingstad DR, Rogers MJ. Validity concerns in the measurement of women's and men's report of intimate partner violence. *Sex Roles*. (2013) 69:149–67. doi: 10.1007/s11199-013-0264-5
20. Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised Conflict Tactics Scales (CTS2): development and preliminary psychometric data. *J Fam Issues*. (1996) 17: 283–316. doi: 10.1177/019251396017003001
21. Jaeschke R, Guyatt GH, Sackett DL. Users' guides to the medical literature: III. How to use an article about a diagnostic test. B. What are the results and will they help me in caring for my patients? *JAMA*. (1994) 271:703–7. doi: 10.1001/jama.271.9.703
22. Kohl M. Performance measures in binary classification. *Int J Stat Med Res*. (2012) 1:79–81. doi: 10.6000/1929-6029.2012.01.01.08
23. Davis KC, Gilmore AK, Stappenbeck CA, Balsan MJ, George WH, Norris J. How to score the sexual experiences survey? A comparison of nine methods. *Psychol Violence*. (2014) 4: 445–61. doi: 10.1037/a0037494
24. McElvaney R, Greene S, Hogan D. To tell or not to tell? Factors influencing young people's informal disclosures of child sexual abuse. *J Interpers Violence*. (2014) 29:928–47. doi: 10.1177/0886260513506281
25. Chan KL. Comparison of parent and child reports on child maltreatment in a representative household sample in Hong Kong. *J Fam Violence*. (2012) 27:11–21. doi: 10.1007/s10896-011-9405-1
26. Chan KL. Gender symmetry in the self-reporting of intimate partner violence. *J Interpers Violence*. (2012) 27: 263–86. doi: 10.1177/0886260511416463
27. Chan KL. Are parents reliable in reporting child victimization? Comparison of parental and adolescent reports in a matched Chinese household sample. *Child Abuse Negl*. (2015) 44:170–83. doi: 10.1016/j.chiabu.2014.11.001
28. Schofield MJ, Powers JR, Loxton D. Mortality and disability outcomes of self-reported elder abuse: a 12-year prospective investigation. *J Am Geriatr Soc*. (2013) 61:679–85. doi: 10.1111/jgs.12212
29. Dong X, Simon MA, Evans DA. Prevalence of self-neglect across gender, race, and socioeconomic status: findings from the Chicago Health and Aging Project. *Gerontol*. (2012) 58: 258–68. doi: 10.1159/000334256
30. Cooper C, Selwood A, Livingston G. The prevalence of elder abuse and neglect: a systematic review. *Age Ageing*. (2008) 37:151–60. doi: 10.1093/ageing/afm194

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Factors Influencing the Adoption of Online Health Consultation Services: The Role of Subjective Norm, Trust, Perceived Benefit, and Offline Habit

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The cyberspace plays an important role in improving the quality, equity, and efficiency of health services. Studying people's adoption of online health services, such as online health consultation services (OHCS) can benefit both industry and policy in the health service sector. This paper investigates influencing factors and paths of people's intention of adopting OHCS by employing the extended valence framework, with our new contribution of integrating subjective norm and offline habit into the model. Five hundred forty-three university students participated in the survey. Structural equation models and Sobel-Goodman tests were applied to test the models. The results show that subjective norm ($\beta = 0.077$, $p = 0.041$), trust in providers ($\beta = 0.194$, $p = 0.002$) and perceived benefit ($\beta = 0.463$, $p < 0.001$) positively affect the intention to adopt OHCS, while offline habit ($\beta = -0.111$, $p = 0.026$) has a negative effect. However, the association of perceived risk ($\beta = -0.062$, $p = 0.315$) and adoption is not supported. Moreover, trust in providers plays a mediating role between subjective norm and the intention of adopting, while perceived benefit mediates the relationship between trust in providers and the intention of adopting. This study highlights the importance of trust, subjective norm, perceived benefit, and persisting habits in promoting the adoption of OHCS.

Keywords: online health consultation service, adoption, subjective norm, habit, extended valence framework

INTRODUCTION

Information and communication technologies (ICTs) have been widely used to support and to deliver health services recently (1) because ICTs' products [e.g., health information systems (HIS)] can improve the quality, efficiency, and equity of health care services delivery (2). For example, online health services (OHS), as one health information system, comprise online health consultation services (OHCS), information seeking services, and online health forums. OHS can provide health services to anyone with medical demands online at any time (3) and can overcome geographic constraints to provide services for users far away from health institutions (4). Thus, OHS has been deemed as an extension of traditional offline health services (3). With the characteristics of vast territory and inequality of socioeconomic development in China, OHS has been proposed by the Chinese government as an important option of improving the equity

and efficiency of health services in China (5, 6). Meanwhile, the OHS industry is emerging and companies, such as “Hao Daifu Zaixian,” “Clove Doctor,” or “Chun Yu Doctor,” have been started, widely advertised, and being noted by the public.

Nevertheless, the public’s adoption of OHS is still relatively low in China as compared with more developed countries (7). For example, the 39th Statistical Report on the Development of Chinese Internet Network showed that only 10.8% of Chinese Internet users sought health information online in 2016 (8). In comparison, 72% of U.S. adults who use the internet had searched online for health information in 2012 (9). Furthermore, a study found that less than only one percent of the visitors of the famous Chinese OHS company called “Hao Daifu Zaixian” consulted with doctors online (3). Obviously, there are still shortcomings in Chinese OHS, especially in OHCS. OHCS can provide a new channel to promote the public to obtain more diagnostic information and manage themselves and their families’ health, and thereby improve the quality of health care. Meanwhile, growth in OHCS usage can further strengthen the development of the OHS industry. However, the low usage rates of OHCS may make it difficult to exert a significant effect on health services. Therefore, understanding the reasons for such low usage rate will be useful for service providers in formulating strategies aimed at increasing OHCS adoption.

OHS research papers account only for a small proportion of HIS research, based on our literature research in PubMed and Web of Science. Most of the existing literature on HIS focuses on the implementation of HIS, such as Clinical Information System, Computerized Physician Order Entry System, Electronic Health Records or Electronic Medical Record, in health institutions. For example, the determinants of adoption of these HIS have been examined from the perspective of physicians (10, 11), nurses (2, 12), and medical institutions (13, 14). Some other studies explored how to design a HIS (15, 16) or evaluated the implementation of a HIS (17, 18).

Furthermore, among the OHS literature, research on individuals’ adoption of OHCS is very limited. Although some studies have examined the factors that influence consumers to adopt OHS, most of them explored the issue of health information seeking. Trust, perceived risk, perceived usefulness, and perceived health condition are common factors that were found to influence consumers’ information seeking behaviors in these studies (4, 19, 20). However, information seeking and online consultations are two related but different behaviors because information seeking is usually unilateral, but online consultation involves interaction between consumers and doctors. Indeed, several articles explored behaviors toward a non-specific comprehensive OHS, which included information seeking, online registration, online consultation, and patient education rather than the information seeking alone (3, 7, 21). No studies that solely concentrated on OHCS were identified in our literature reviews, and thus we developed the present study to contribute to closing this gap.

This study focuses on the adoption of OHCS from the perspective of the decision-making process. OHS is the application of e-commerce in the healthcare context (7), so the adoption of OHCS, as a part of OHS usage, can be

considered as an e-commerce behavior. Previous studies have found that perceived benefit and risk, as well as trust are important determinants in consumers’ decision-making process of purchase and adoption of online services (19, 22–25). Hence, the extended valence framework (26) including benefit perception, risk perception, and trust was adopted to guide this research. Moreover, using OHCS involves changes in habits of receiving offline medical services (3), and subjective norms are also essential for behavioral change of consumers (27). We this integrated subjective norm and offline habit in the extended valence framework. In short, this paper explores motivational and inhibiting factors of OHCS adoption to improve our current understanding of consumers’ decision-making processes regarding OHCS.

THEORETICAL FOUNDATION AND HYPOTHESES

The Extended Valence Framework

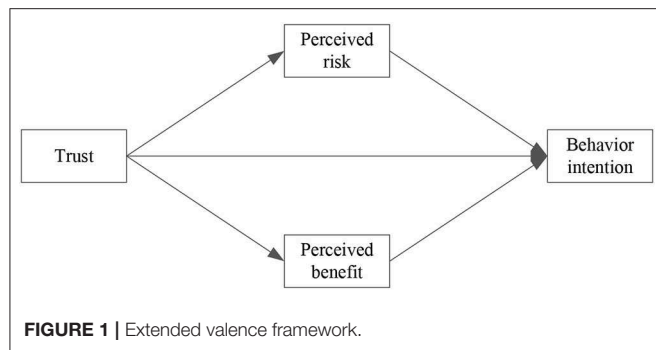
The theoretical foundation of this study is the extended valence framework. The valence framework is a well-established theory deriving from economic and psychological theories in behavioral research (28, 29). Perceived risk and benefit are the two foundational aspects regarding consumers’ decision-making and consumers tend to maximize the positive value (perceived benefit) and minimize the negative impacts (perceived risk) of a product or service when they make decision of purchasing it according to the valence framework (30, 31). The valence framework performs well in understanding individual’s behavior because by considering both negative and positive attributes in decision-making simultaneously (32).

Kim developed the extended valence framework by integrating trust into the valence framework (26). The extended valence framework states that trust, perceived risk and perceived benefit directly affect consumers’ purchase intention in one way, and in an indirect way, trust influences the purchase intention through perceived risk and perceived benefit (**Figure 1**). The extended valence framework has been applied in studies regarding e-commerce, and has been considered a useful and valid theoretical framework to guide our understanding of people’s behaviors in the e-commerce context (33), including online health information seeking behavior (4). Moreover, a benefit-risk evaluation may help strategy-planners to make more updated, informed, and effective management decisions (34). Therefore, the extended valence framework is adopted in this paper to promote the understanding of the individual’s adoption of OHCS.

Hypotheses

Perceived Risk

Perceived risk is considered as a salient inhibitor of the adoption of online services, because individuals may experience certain levels of risk due to the uncertainty and uncontrollability of the cyberspace (26). Perceived risk is a multifaceted concept (24) and varies according to types of products or services (35). In the context of this study, perceived risk refers to privacy and security risk concerns. Privacy and security risk involves the collection,



use, and disclosure of personal information (36), as well as uncertain consequences of actions based on information and guidance provided by an online doctor (37). Health information technology may aggravate individuals' privacy concerns over the potential misuse of personal health information (38). Empirical findings have shown that there is a negative association between online privacy and security concerns and the use of online health services (21, 39). Thus, we hypothesize:

H1. Perceived risk has a negative effect on the adoption of OHCS.

Perceived Benefit

Perceived benefit is defined as a consumer's belief about the extent to which he/she will become better off through the use of certain online service (31). Evidence from prior studies has shown that perceived benefit exerted a positive and significant effect on customers' behavioral intention (23, 38, 40). OHCS as one of many internet-based services which may bring about potential benefits for consumers, such as cost and time saving (41), which have been identified as relative benefits as compared with traditional offline services (28). Accordingly, if an individual perceived a higher degree of benefits, he/she would be more likely to adopt OHCS. Thus, we hypothesize:

H2. Perceived benefit has a positive effect on the adoption of OHCS.

Trust

Trust either can be defined as one's willingness to rely upon another (42), or as the belief in dependability and honesty (43). In this study, trust refers to the trust in OHCS providers which include both online platform and online doctors. Furthermore, trust in OHCS providers is defined as the individual's confidence in the provider's integrity and dependability (44), and the belief that OHCS providers have attributes that are beneficial to consumers (37). Individuals' trust is considered as one of the most important psychological factors influencing online behaviors (31). Prior studies found that there is a positive association between trust and behavioral intention (22, 26). It's likely that people with a higher degree of trust feel less uncertainty and believe that the service will improve their effectiveness in managing their health (4). Thus, trust can influence consumers' purchase decision making both directly and indirectly through perceived benefits and risks, i.e., trust can have a positive impact

on perceived benefits and a negative influence on perceived risks. In sum, trust influences consumers' intention of purchasing in e-commerce both directly and indirectly through perceived risks and benefits (26). Thus, we hypothesize:

H3. Trust in providers has a positive effect on the adoption of OHCS.

H4. Trust in providers has a negative effect on the risk perception of OHCS.

H5. Trust in providers has a positive effect on the benefit perception of OHCS.

Subjective Norm

Subjective norm refers to how an individual thinks he/she should behave and how their behavior would be judged by others in a specific cultural and social environment (45). According to the Theory of Reasoned Action, individual's intention of performing a given behavior is influenced by normative beliefs—the views (whether the individual agrees or not) regarding one behavior developed by important others, such as peers, friends or relatives (46, 47). Thus, people may shape their behavioral intentions based on how they believe significant others will view their behaviors. Previous studies have found that subjective norm affects online health-related behavioral intention positively (19, 48). Therefore, we hypothesize:

H6. Subjective norm has a positive effect on the adoption of OHCS.

In the current study, the subjective norm is also considered to be a determinant of trust, perceived benefit, and perceived risk. Li et al. (49) found that when people do not know a system well, they may rely on the opinions of others significant to them, and then develop trust belief toward the system accordingly (49). Moreover, prior research found that subjective norm directly affects trust (50, 51). Regarding the perceived benefit and perceived risk, few studies in the online health context have simultaneously incorporated the association between subjective norm and perceived benefit, and the association between subjective norm and perceived risk. However, it has been found in other information systems related research that subjective norm influences perceived usefulness positively (52, 53) and motivates users to reveal personal information (54). In other words, subjective norm, to a certain extent, can enhance individual perception of benefits and reduce the risk perception of private information. Therefore, we hypothesize:

H7. Subjective norm has a positive effect on trust in providers.

H8. Subjective norm has a positive effect on perceived benefit.

H9. Subjective norm has a negative effect on perceived risk.

Offline Habit

Habits can shape human's decision process, and are considered as a critical factor influencing people's behavior in the e-commerce context (55). A habit is an individual's repeated, unconscious and automatic behavior (56). Studies have shown that habits may keep individual from switching to new technologies (57). Thus, people's habits of using offline service channels may have a negative effect on their intention to switch to the online service channel (28). Regarding health services, if an individual is used to visiting doctors in hospitals (offline channel), she/he would be

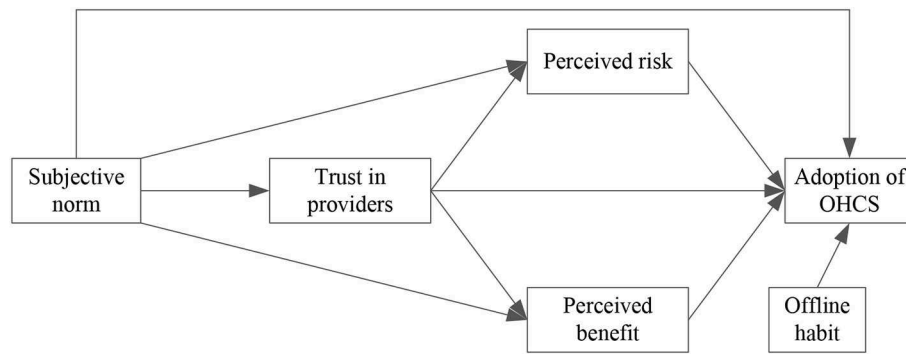


FIGURE 2 | Research model.

TABLE 1 | Measurement items, factor loading, and characteristics of variables.

Variables	Items	FL	Mean (SD)	Range
Subjective norm	SN1: People who influence my behavior (would think/think) that I should use the OHCS.	0.875	8.39 (2.42)	3–15
	SN2: People who are important to me (would think/think) that I should use the OHCS.	0.896		
	SN3: People who are in my social circle (would think/think) that I should use the OHCS.	0.880		
Trust in providers	TP1: I would characterize OHCS providers as honest.	0.670	22.24 (3.98)	7–35
	TP2: I believe that the health service provided by OHCS platform is useful.	0.600		
	TP3: The OHCS platform performs its role as health service providers very well.	0.597		
	TP4: I have confidence in relying on OHCS platforms to complete a health consultation or diagnosis.	0.681		
	TP5: Doctors on the OHCS platform have medical qualifications.	0.794		
	TP6: The consultation or diagnosis provided by doctors on OHCS platforms is reliable	0.769		
	TP7: In my opinion, doctors on the OHCS platform are trustworthy.	0.806		
Perceived risk	PR1: Providing personal health information online is unsafe.	0.576	18.36 (3.14)	5–25
	PR2: I think it is risky to provide personal information to OHCS providers.	0.808		
	PR3: I think it is risky to provide personal health information to doctors on OHCS platforms.	0.797		
	PR4: I would hesitate to provide my personal information (such as name, address, health condition, bank information, and phone number, etc.) to OHCS platforms.	0.719		
	PR5: I think it is risky to make a decision (such as taking medicine, controlling diet, etc.) based on the diagnosis provided by the doctors on the OHCS platform.	0.631		
Perceived benefit	PB1: Using OHCS can be of benefit to me in managing my health.	0.793	21.35 (3.76)	6–30
	PB2: Using OHCS can increase my knowledge of my personal health conditions.	0.804		
	PB3: Using OHCS can help to relieve stresses about my symptoms or my worries about symptoms.	0.691		
	PB4: Using OHCS will be useful for my health.	0.766		
	PB5: Compared with going to the hospital, using OHCS can save time.	0.706		
	PB6: Compared with going to the hospital, using OHCS can save medical expenses.	0.666		
Offline habit	OH1: Whenever I need to see a doctor or have a health consultation, I will choose to go to hospitals or clinics without even being aware of making another choice.	0.737	15.77 (2.50)	4–20
	OH2: Whenever I need to see a doctor or have a health consultation, I unconsciously start going to hospitals or clinics.	0.879		
	OH3: Choosing to go to hospitals or clinics when I need to see a doctor or have a health consultation is something I do unconsciously.	0.844		
	OH4: In general, I am accustomed to taking the offline channel (going to hospitals or clinics) for medical treatment or health consultation.	0.828		
Adoption of OHCS	AO1: I intend to use OHCS to consult health issues when needed in the future.	0.811	10.27 (2.01)	3–15
	AO2: I predict that I will use OHCS to consult health issues when needed in the future.	0.862		
	AO3: I plan to use OHCS to consult health issues when needed in the future.	0.845		

FL, factor loading; SD, standard deviation.

more willing to continue to use the offline channel rather than switching to online services. Therefore, we hypothesize:

H10. Offline habit has a negative effect on the adoption of OHCS.

Based on the hypotheses mentioned above, we propose our research model as depicted in **Figure 2**.

METHODS

Participants and Procedures

The participants were university students, which were sampled by convenience. University students represent a large proportion of active online consumers (31), and the younger generation is the most active population participating in online transactions (58). Moreover, students younger than 30 years are the largest group of internet users, representing the majority of Internet users in China (28). Moreover, prior e-service documents including research on OHS also sampled from student populations (19, 28). Here, students from two universities in China were surveyed. We designed a web-based questionnaire, and linkage of the questionnaire was delivered to both undergraduate and graduate students via social network applications (WeChat and QQ). The questionnaire contained instructions and an explanation of the study but did not collect any information that would have made the person identifiable. The participation of each student was completely voluntary, and they could withdraw from the study at any stage. Eventually, 543 valid questionnaires were collected.

Measurements

The adoption of OHCS (AO) was assessed by three items adapted from an instrument created by Venkatesh et al. (59). Similarly, subjective norm (SN) also included three items adapted from Venkatesh et al. (60). Trust in providers (TP) was measured by seven items (four items adapted from Cater and Bélanger (61) and Mou et al. (4) and three self-constructed items). Perceived risk (PR) was assessed by five items adapted from McKnight et al. (62) and Yi et al. (37). Perceived benefit (PB) was measured by six items including four items adapted from Mou et al. (4) and Zhang et al. (7) and two self-developed items. Offline habit (OH) was measured with four items which were adapted from Zhang et al. (7). The items are listed in **Table 1**. All items were assessed using five-point Likert scales ranging from strongly disagree (1) to strongly agree (5).

Statistical Analysis

Before hypotheses testing, we first evaluated the measurement model including composite reliability, convergent validity, and discriminant validity. Then, structural equation modeling (SEM) was conducted to test the hypotheses. Goodness-of-fit indices and the path coefficients with *p*-values were reported. Based on recommendations of Wang and Lai (63), the ratio of Chi-square values (χ^2) to the degrees of freedom (χ^2/df) should be <3 . The values of the Tucker-Lewis fit index (TLI), comparative fit index (CFI), goodness-of-fit index (GFI), and normalized fit index (NFI) should be higher than 0.9, while root-mean-square residual (RMR) and root-mean-square-error of approximation (RMSEA) should be <0.8 . Besides, we conducted a mediation

TABLE 2 | Characteristic of respondents.

Items		Frequency	Percent (%)
Gender	Female	349	64.27
	Male	194	35.73
Being a graduate student	No	298	54.88
	Yes	245	45.12
Major	Medicine	168	30.94
	Else	375	69.06
Experience of obtaining health information online	No	189	34.81
	Yes	354	65.19
Expense	<1,000	100	18.42
	1,000–2,000	361	66.48
	2,001–3,000	55	10.13
	More than 3,000	27	4.97
Health condition (Frequency of seeing a doctor)	Never	18	3.31
	Rarely	205	37.75
	Sometimes	224	41.25
	Usually	96	17.68

analysis to further examine mediating effects. Sobel-Goodman tests were applied to test the presence of mediation. Amos 21.0 was used for the SEM, and Stata/MP 14.0 was used for all other analyzes.

RESULT

Descriptive Results

Among the 543 qualified respondents, 64.27% were female; 45.12% were graduate students, and 30.94% were specialized in Medicine. Detailed results are shown in **Table 2**. Mean values (standard deviations) of AO (adoption of online health consultation service), SN (subjective norm), TP (trust in providers), PR (perceived risk), PB (perceived benefit), and OH (offline habit) were 10.27 (2.01), 8.39 (2.42), 22.24 (3.98), 18.36 (3.14), 21.35 (3.76), and 15.77 (2.50), respectively (**Table 1**).

Measurement Model Evaluation

The measurement model aims to assess reliability and validity. We used Cronbach's alpha (CA) and composite reliability (CR) to evaluate the construct reliability. The results of all CA test ranged from 0.788 to 0.914, and CR values ranged from 0.835 to 0.915 (**Table 3**). Since both CA and CR for each construct were higher than the minimum cutoff value of 0.7 (64), construct reliability was supported.

Concerning validity, we assessed both convergent validity and discriminant validity. Convergent validity was assessed by factor loadings and average variance extracted (AVE). The factor loadings and AVE of all constructs were higher than the suggested value of 0.5 (65), indicating a good convergent validity. Additionally, the square root of AVE for each construct was higher than its correlation coefficient with any other construct. Therefore, discriminant validity was acceptable.

TABLE 3 | Validity and reliability of variables.

	CA	CR	AVE	SN	TP	PR	PB	OH	AO
SN	0.914	0.915	0.781	0.884					
TP	0.907	0.874	0.500	0.467	0.707				
PR	0.788	0.835	0.507	−0.190	−0.318	0.712			
PB	0.887	0.878	0.547	0.326	0.620	−0.170	0.740		
OH	0.847	0.894	0.678	−0.149	−0.073	0.314	0.024	0.823	
AO	0.886	0.878	0.705	0.331	0.500	−0.207	0.501	−0.131	0.840

CA, Cronbach's alpha; CR, composite reliability; AVE, average variance extracted. The bold diagonally are the square root of AVE.

TABLE 4 | Path coefficients and the result of hypotheses test.

Hypotheses	Path coefficients	Sig.	Findings
H1: PR→AO	−0.062	$P = 0.315$	Not supported
H2: PB→AO	0.463	$P < 0.001$	Supported
H3: TP→AO	0.194	$P = 0.002$	Supported
H4: TP→PR	−0.260	$P < 0.001$	Supported
H5: TP→PB	0.493	$P < 0.001$	Supported
H6: SN→AO	0.077	$P = 0.041$	Supported
H7: SN→TP	0.420	$P < 0.001$	Supported
H8: SN→PB	0.017	$P = 0.593$	Not supported
H9: SN→PR	−0.019	$P = 0.570$	Not supported
H10: OH→AO	−0.111	$P = 0.026$	Supported

Structural Model Evaluation

We first tested the fitness index of the structural model. The result showed that the structural model had a good fit ($\chi^2 = 802.096$, $\chi^2/df = 2.416$, $RMR = 0.040$, $RMSEA = 0.051$, $GFI = 0.901$, $NFI = 0.916$, $TLI = 0.942$, $CFI = 0.945$). Results of hypotheses testing and the SEM are shown in **Table 4** and **Figure 3**, respectively. Perceived benefit ($\beta = 0.463$, $p < 0.001$) significantly and positively influenced the adoption of OHCS, while the effect of perceived risk ($p = 0.315$) on the adoption of OHCS was not statistically significant. Trust in providers significantly and positively affected the adoption of OHCS ($\beta = 0.194$, $p = 0.002$) and perceived benefit ($\beta = 0.493$, $p < 0.001$), but negatively affected perceived risk ($\beta = -0.260$, $p < 0.001$). Subjective norm was positively correlated with the adoption of OHCS ($\beta = 0.077$, $p = 0.041$) and trust in providers ($\beta = 0.420$, $p < 0.001$). Nevertheless, none of its effects on perceived benefit ($p = 0.593$) or on the perceived risk ($p = 0.570$) was statistically significant. Moreover, offline habit ($\beta = -0.111$, $p = 0.026$) affected the adoption of OHCS negatively. In sum, perceived benefit, trust in providers, subjective norm and offline habit had a significant direct effect on the adoption of OHCS, and the structural model could explain 38.4% of the variation in OHCS adoption ($R^2 = 0.384$).

Post-hoc Analysis

Based on the result of the structural model, we further conducted a *post-hoc* analysis to test the mediating effect of trust in providers

in the relation between subjective norm and the adoption of OHCS, and to test the mediating effect of perceived benefit in the relation between trust in providers and the adoption of OHCS. We confirmed a significant indirect effect of the subjective norm ($\beta = 0.172$, $p < 0.001$) on adoption through trust in providers, which accounted for 61.6% of the total effect that subjective norm had on adoption (**Table 5**). Moreover, a significant indirect effect of trust in providers ($\beta = 0.093$, $p < 0.001$) on adoption through perceived benefit was also confirmed, accounting for 36.9% of the total effect.

DISCUSSION

This study enriches the extended valence framework by integrating subjective norm and offline habit into the extended valence framework in order to investigate the facilitators and barriers of OHCS adoption. To the best of our knowledge, this is the first study about people's decision-making regarding the adoption of OHCS in China. Our results show that trust in providers, perceived benefit, subjective norm, and offline habit significantly affect the adoption of OHCS, while the impact of perceived risk on adoption is not supported. 38.4% variation of the adoption of OHCS is explained by our proposed model, and there are four important findings.

First, the extended valence framework can partly interpret the adoption of OHCS. Perceived benefit, as expected, influences the adoption of OHCS positively—students with a higher degree of perceived benefit are more likely to adopt the OHCS. Also, consistent with existing literature (4, 19), trust in providers has a positive effect on the adoption of OHCS. Moreover, such positive effect is partly mediated by perceived benefit. Therefore, both perceived benefit and trust in providers are critical determinants of OHCS usage.

However, the association between perceived risk and the adoption of OHCS is not significant in this study. Prior studies on OHS have found that perceived risk had a negative effect on behavioral intention toward using health service (7, 39). One possible reason is that online health consultation behavior is different from other OHS behaviors (e.g., health information seeking). Investigations in South Africa and China found that perceived risk plays a role in dampening people's online health information acceptance behavior (4) or intention to use comprehensive OHS (7). The inconsistent results indicate that there is a need to conduct more research specifically

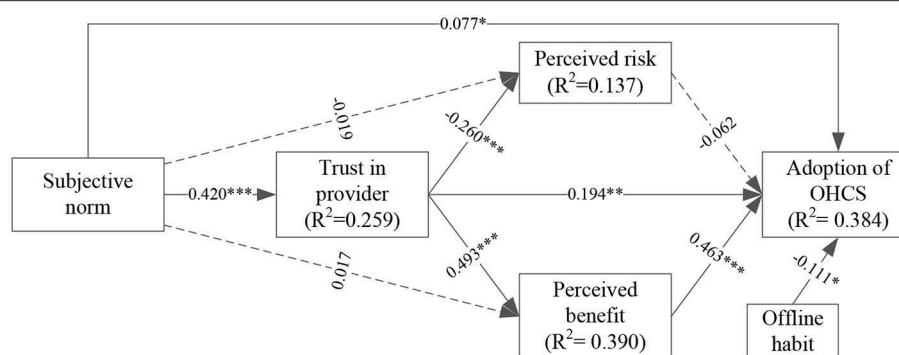


FIGURE 3 | The structural model and R^2 values. dashed lines represent unsupported paths. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

TABLE 5 | Mediation result.

		B	S.E.	Sobel z (% of total effect)
Mediation of TP	Direct effect			
	SN	0.107**	0.035	
	TP	0.221***	0.021	
	Indirect effect			7.961 (61.6%)
	SN on AO through TP	0.172***	0.022	
Mediation of PB	Direct effect			
	TP	0.159***	0.023	
	PB	0.159***	0.025	
	Indirect effect			6.078 (36.9%)
	TP on AO through PB	0.093***	0.015	

Gender, major, being a graduate student, experience of obtaining health information online, monthly expense and health condition were included in the analysis but not reported in this table. ** $p < 0.01$, *** $p < 0.001$.

focused on OHCS. Another possible explanation could be that the respondents are university students, who have a strong perception of control in online behavior. This makes them believe that they can identify potential risks and avoid risky behavior when they adopt OHCS.

This study confirms a positive associations between subjective norm and the intention of using OHCS, which is consistent with previous findings related to e-services (e.g., e-banking) (27, 66). Compared with other studies that only analyzed the direct relationship between subjective norm and intention of adoption (48, 67), we further found that trust in providers mediated the association of subjective norm and OHCS adoption. In other words, subjective norm directly influences OHCS adoption, but also influences trust in providers first, and then influences OHCS adoption indirectly through trust in providers. Obviously, both direct and indirect effect of subjective norm on the adoption of OHCS show that subjective norm must be taken into account when promoting and implementing OHCS. Unfortunately, associations of subjective norm with perceived benefit and perceived risk are not supported, and such associations deserve to be further explored.

Offline habit is the only negative factor that influences the adoption of OHCS. Habit is considered as an automatic

behavioral process, which makes individuals do not evaluate the benefit and cost of their ongoing behavior (68). Hence, habitual behavior causes a lack of motivation to change ongoing behavior (7). Individuals who are used to offline health services were reluctant to transfer to OHS (28). This indicates that the low usage rate of OHCS in China may be due to people's habit of accessing medical services offline. Despite the rapid development of information and communication technology, traditional offline channels (going to hospitals or clinics for medical services) are still the first choice for people to see a doctor. Therefore, OHCS providers should take positive strategies to encourage potential consumers to adopt online services and eliminate the adverse effects of offline habits gradually (28), e.g., by enhancing individual eHealth literacy through educational programs (1).

This study has some limitations. First, the measurement of perceived risk only consisted of privacy and security concerns, while online risk should contain more facets. This implies that H1 can only reflect the non-significant association of privacy and security risk with the adoption of OHCS. Second, the respondents of the present study were only university students, and generalizations to other potential OHCS consumer groups cannot be made. Thus, studies with more representative samples should be conducted in the future. Third, this study studied behavioral intention rather than actual behavior regarding OHCS adoption. It may thus suffer from information bias, since intention and behavior are closely related but not necessarily equivalent.

CONCLUSION

This study explored factors influencing of the adoption of OHCS by integrating offline habit and subjective norm into the extended valence framework. Subjective norm, trust in providers and perceived benefit were found to play promoting roles regarding individuals' OHCS adoption behavior, while habit had an inhibitory effect. The habit of using offline channels to obtain health services can play an important role in explaining low usage rate of OHCS in China. To promote the adoption of OHCS, the negative effect of offline habit should be

considered besides the strengthening of trust, subjective norms and perceived benefits.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

AUTHOR CONTRIBUTIONS

ZG, ZH, XL, CY, and JR have made a direct, intellectual contribution to this study. ZG and ZH designed and wrote most part of the paper and conducted the data analysis.

XL, CY, and JR were major contributors of data collection and paper revision. All authors have read and approved the final version.

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REFERENCES

- Kim H, Xie B. Health literacy in the eHealth era: a systematic review of the literature. *Patient Educ Couns.* (2017) 100:1073–82. doi: 10.1016/j.pec.2017.01.015
- Hung S-Y, Tsai JC-A, Chuang C-C. Investigating primary health care nurses' intention to use information technology: an empirical study in Taiwan. *Decis Support Syst.* (2014) 57:331–42. doi: 10.1016/j.dss.2013.09.016
- Zhang X, Guo X, Lai K, Yin C, Meng F. From offline healthcare to online health services: the role of offline healthcare satisfaction and habits. *J Electron Commer Res.* (2017) 18:138–54. Available online at: http://www.jecr.org/sites/default/files/2017vol18no2_Paper3.pdf
- Mou J, Shin D-H, Cohen J. Health beliefs and the valence framework in health information seeking behaviors. *Info Technol People.* (2016) 29:876–900. doi: 10.1108/ITP-06-2015-0140
- State Council of the People's Republic of China. *Guidance on Promoting the "Internet + " Initiative.* (2015) Available online at: http://www.gov.cn/zhengce/content/2015-07/04/content_10002.htm (accessed January 13, 2019)
- General Office of the State Council of the People's Republic of China. *Opinions on Promoting the Development of "Internet + Medical Health".* (2018) Available online at: http://www.gov.cn/zhengce/content/2018-04/28/content_5286645.htm (accessed January 13, 2019)
- Zhang X, Guo X, Wu Y, Lai K, Vogel D. Exploring the inhibitors of online health service use intention: a status quo bias perspective. *Inf Manage.* (2017) 54:987–97. doi: 10.1016/j.im.2017.02.001
- China Internet Network Information Center. *The 39th Statistical Report on the Development of Chinese Internet Network.* (2017) Available online at: <http://www.cac.gov.cn/cnnic39/> (accessed January 13, 2019)
- Fox S, Duggan M. *Health Online 2013 | Pew Research Center.* (2013) Available online at: <http://www.pewinternet.org/2013/01/15/health-online-2013/> (accessed January 13, 2019)
- Kaipio J, Lääveri T, Hyppönen H, Vainiomäki S, Reponen J, Kushniruk A, et al. Usability problems do not heal by themselves: National survey on physicians' experiences with EHRs in Finland. *Int J Med Inform.* (2017) 97:266–81. doi: 10.1016/j.ijmedinf.2016.10.010
- Sidek YH, Martins JT. Perceived critical success factors of electronic health record system implementation in a dental clinic context: an organisational management perspective. *Int J Med Inform.* (2017) 107:88–100. doi: 10.1016/j.ijmedinf.2017.08.007
- Alquraini H, Alhashem AM, Shah MA, Chowdhury RI. Factors influencing nurses' attitudes towards the use of computerized health information systems in Kuwaiti hospitals. *J Adv Nursing.* (2007) 57:375–81. doi: 10.1111/j.1365-2648.2007.04113.x
- Wang BB, Wan TTH, Burke DE, Bazzoli GJ, Lin BYJ. Factors influencing health information system adoption in American hospitals. *Health Care Manage Rev.* (2005) 30:44–51. doi: 10.1097/00004010-200501000-00007
- Yoshida Y, Imai T, Ohe K. The trends in EMR and CPOE adoption in Japan under the national strategy. *Int J Med Inform.* (2013) 82:1004–11. doi: 10.1016/j.ijmedinf.2013.07.004
- Urda D, Ribelles N, Subirats JL, Franco L, Alba E, Jerez JM. Addressing critical issues in the development of an oncology information system. *Int J Med Inform.* (2013) 82:398–407. doi: 10.1016/j.ijmedinf.2012.08.001
- Batley NJ, Osman HO, Kazzi AA, Musallam KM. Implementation of an emergency department computer system: design features that users value. *J Emerg Med.* (2011) 41:693–700. doi: 10.1016/j.jemermed.2010.05.014
- Yusof MM, Kuljis J, Papazafeiropoulou A, Stergioulas LK. An evaluation framework for health information systems: human, organization and technology-fit factors (HOT-fit). *Int J Med Inform.* (2008) 77:386–98. doi: 10.1016/j.ijmedinf.2007.08.011
- Petter S, Fruhling A. Evaluating the success of an emergency response medical information system. *Int J Med Inform.* (2011) 80:480–9. doi: 10.1016/j.ijmedinf.2011.03.010
- Mou J, Shin D-H, Cohen J. Understanding trust and perceived usefulness in the consumer acceptance of an e-service: a longitudinal investigation. *Behav Inf Technol.* (2017) 36:125–39. doi: 10.1080/0144929X.2016.1203024
- Xiao N, Sharman R, Rao HR, Upadhyaya S. Factors influencing online health information search: an empirical analysis of a national cancer-related survey. *Decis Support Syst.* (2014) 57:417–27. doi: 10.1016/j.dss.2012.10.047
- Chang J. Privacy and security concerns in online health services. *Appl Econ Lett.* (2018) 25:1351–4. doi: 10.1080/13504851.2017.1420878
- Gefen D, Karahanna E, Straub DW. Trust and TAM in online shopping: an integrated model. *MIS Q.* (2003) 27:51–90. doi: 10.2307/30036519
- Lee M-C. Factors influencing the adoption of internet banking: an integration of TAM and TPB with perceived risk and perceived benefit. *Electron Commer Res Appl.* (2009) 8:130–41. doi: 10.1016/j.elerap.2008.11.006
- Tai Y-M, Ku Y-C. Will stock investors use mobile stock trading? A benefit-risk assessment based on a modified Utaut model. *J Electron Commer Res.* (2013) 14:67. Available online at: http://www.jecr.org/sites/default/files/14_01_p5.pdf
- Choi J, Lee A, Ok C. The effects of consumers' perceived risk and benefit on attitude and behavioral intention: a study of street food. *J Travel Tourism Mark.* (2013) 30:222–37. doi: 10.1080/10548408.2013.774916
- Kim DJ, Ferrin DL, Rao HR. Trust and satisfaction, two stepping stones for successful E-commerce relationships: a longitudinal exploration. *Inf Syst Res.* (2009) 20:237–57. doi: 10.1287/isre.1080.0188
- Liao C, Chen J-L, Yen DC. Theory of planning behavior (TPB) and customer satisfaction in the continued use of e-service: an integrated model. *Comput Hum Behav.* (2007) 23:2804–22. doi: 10.1016/j.chb.2006.05.006
- Lu Y, Cao Y, Wang B, Yang S. A study on factors that affect users' behavioral intention to transfer usage from the offline to the online channel. *Comput Hum Behav.* (2011) 27:355–64. doi: 10.1016/j.chb.2010.08.013
- Ozturk AB, Bilgihan A, Salehi-Esfahani S, Hua N. Understanding the mobile payment technology acceptance based on valence theory: a case of restaurant transactions. *Int J Contemp Hospitality Manage.* (2017) 29:2027–49. doi: 10.1108/IJCHM-04-2016-0192
- Peter JP, Tarpey LX. A comparative analysis of three consumer decision strategies. *J Consum Res.* (1975) 2:29–37. doi: 10.1086/208613

31. Kim DJ, Ferrin DL, Rao HR. A trust-based consumer decision-making model in electronic commerce: the role of trust, perceived risk, and their antecedents. *Decis Support Syst.* (2008) 44:544–64. doi: 10.1016/j.dss.2007.07.001
32. Lin J, Wang B, Wang N, Lu Y. Understanding the evolution of consumer trust in mobile commerce: a longitudinal study. *Inf Technol Manage.* (2014) 15:37–49. doi: 10.1007/s10799-013-0172-y
33. Lee ZWY, Chan TKH, Balaji MS, Chong AY-L. Why people participate in the sharing economy: an empirical investigation of Uber. *Internet Res.* (2018) 28:829–50. doi: 10.1108/IntR-01-2017-0037
34. Verhagen H, Tijhuis MJ, Gunnlaugsdóttir H, Kalogeras N, Leino O, Luteijn JM, et al. State of the art in benefit–risk analysis: introduction. *Food Chem Toxicol.* (2012) 50:2–4. doi: 10.1016/j.fct.2011.06.007
35. Kaplan L, Szybillo G, Jacoby J. Components of perceived risk in product purchase - cross-validation. *J Appl Psychol.* (1974) 59:287–91. doi: 10.1037/h0036657
36. Hall JL, McGraw D. For telehealth to succeed, privacy and security risks must be identified and addressed. *Health Aff.* (2014) 33:216–21. doi: 10.1377/hlthaff.2013.0997
37. Yi MY, Yoon JJ, Davis JM, Lee T. Untangling the antecedents of initial trust in web-based health information: the roles of argument quality, source expertise, and user perceptions of information quality and risk. *Decis Support Syst.* (2013) 55:284–95. doi: 10.1016/j.dss.2013.01.029
38. Li Y. The impact of disposition to privacy, website reputation and website familiarity on information privacy concerns. *Decis Support Syst.* (2014) 57:343–54. doi: 10.1016/j.dss.2013.09.018
39. Li H, Wu J, Gao Y, Shi Y. Examining individuals' adoption of healthcare wearable devices: an empirical study from privacy calculus perspective. *Int J Med Inform.* (2016) 88:8–17. doi: 10.1016/j.ijmedinf.2015.12.010
40. Ryu H-S. What makes users willing or hesitant to use Fintech?: the moderating effect of user type. *Ind Manage Data Syst.* (2018) 118:541–69. doi: 10.1108/IMDS-07-2017-0325
41. Lee M-C. Predicting and explaining the adoption of online trading: an empirical study in Taiwan. *Decis Support Syst.* (2009) 47:133–42. doi: 10.1016/j.dss.2009.02.003
42. Doney PM, Cannon JP, Mullen MR. Understanding the influence of national culture on the development of trust. *AMR.* (1998) 23:601–20. doi: 10.5465/amr.1998.926629
43. Kumar N. *The Power of Trust in Manufacturer-Retailer Relationships.* Harvard Business Review. (1996) Available online at: <https://hbr.org/1996/11/the-power-of-trust-in-manufacturer-retailer-relationships> (accessed January 21, 2019)
44. Bhattacharjee A. Individual trust in online firms: scale development and initial test. *J Manage Inf Syst.* (2002) 19:211–41. doi: 10.1080/07421222.2002.11045715
45. Venkatesh V, Morris MG. Why don't men ever stop to ask for directions? Gender, social influence, and their role in technology acceptance and usage behavior. *MIS Q.* (2000) 24:115–39. doi: 10.2307/3250981
46. Ajzen I. The theory of planned behavior. *Org Behav Hum Decis Processes.* (1991) 50:179–211. doi: 10.1016/0749-5978(91)90020-T
47. Fishbein M, Ajzen I. *Predicting and Changing Behavior.* 1st ed. New York, NY;Hove: Routledge (2015).
48. Zhao Y, Ni Q, Zhou R. What factors influence the mobile health service adoption? A meta-analysis and the moderating role of age. *Int J Inf Manage.* (2018) 43:342–50. doi: 10.1016/j.ijinfomgt.2017.08.006
49. Li X, Hess TJ, Valacich JS. Why do we trust new technology? A study of initial trust formation with organizational information systems. *J Strateg Inf Syst.* (2008) 17:39–71. doi: 10.1016/j.jsis.2008.01.001
50. Wu J-H, Shen W-S, Lin L-M, Greenes RA, Bates DW. Testing the technology acceptance model for evaluating healthcare professionals' intention to use an adverse event reporting system. *Int J Qual Health Care.* (2008) 20:123–9. doi: 10.1093/intqhc/mzm074
51. Chaouali W, Ben Yahia I, Souiden N. The interplay of counter-conformity motivation, social influence, and trust in customers' intention to adopt Internet banking services: the case of an emerging country. *J Retailing Consum Serv.* (2016) 28:209–18. doi: 10.1016/j.jretconser.2015.10.007
52. Venkatesh V, Davis FD. A Theoretical extension of the technology acceptance model: four longitudinal field studies. *Manage Sci.* (2000) 46:186–204. doi: 10.1287/mnsc.46.2.186.11926
53. Watjatrakul B. Intention to use a free voluntary service: the effects of social influence, knowledge and perceptions. *J Syst Info Tech.* (2013) 15:202–20. doi: 10.1108/13287261311328903
54. Acquisti A, Gross R. Imagined communities: awareness, information sharing, and privacy on the facebook. In: Danezis G, Golle P, editors. *Privacy Enhancing Technologies.* Berlin: Springer-Verlag Berlin (2006). p. 36–58.
55. Liu C, Liao C, Chuang S, Kuo P, To P. Factors influencing the intended use of web portals. *Online Inf Rev.* (2011) 35:237–54. doi: 10.1108/14684521111128023
56. Chuang Y-F. Pull-and-suck effects in Taiwan mobile phone subscribers switching intentions. *Telecomm Policy.* (2011) 35:128–40. doi: 10.1016/j.telpol.2010.12.003
57. Chen C-F, Chao W-H. Habitual or reasoned? Using the theory of planned behavior, technology acceptance model, and habit to examine switching intentions toward public transit. *Transp Res Part F Traffic Psychol Behav.* (2011) 14:128–37. doi: 10.1016/j.trf.2010.11.006
58. Chuan-Chuan Lin J, Lu H. Towards an understanding of the behavioural intention to use a web site. *Int J Inf Manage.* (2000) 20:197–208. doi: 10.1016/S0268-4012(00)00005-0
59. Venkatesh V, Morris MG, Davis GB, Davis FD. User acceptance of information technology: toward a unified view. *MIS Q.* (2003) 27:425–78. doi: 10.2307/30036540
60. Venkatesh V, Thong JYL, Chan FKY, Hu PJ-H, Brown SA. Extending the two-stage information systems continuance model: incorporating UTAUT predictors and the role of context. *Inf Syst J.* (2011) 21:527–55. doi: 10.1111/j.1365-2575.2011.00373.x
61. Carter L, Bélanger F. The utilization of e-government services: citizen trust, innovation and acceptance factors. *Inf Syst J.* (2005) 15:5–25. doi: 10.1111/j.1365-2575.2005.00183.x
62. McKnight DH, Choudhury V, Kacmar C. The impact of initial consumer trust on intentions to transact with a web site: a trust building model. *J Strateg Inf Syst.* (2002) 11:297–323. doi: 10.1016/S0963-8687(02)00020-3
63. Wang W-T, Lai Y-J. Examining the adoption of KMS in organizations from an integrated perspective of technology, individual, and organization. *Comput Hum Behav.* (2014) 38:55–67. doi: 10.1016/j.chb.2014.05.013
64. Tang Z, Gong Z, Han X, Peng X. Public interest in continued use of Chinese government portals: a mixed methods study. *Telematics Inform.* (2018) 35:2312–25. doi: 10.1016/j.tele.2018.09.011
65. Ogbanufe O, Kim DJ. Comparing fingerprint-based biometrics authentication versus traditional authentication methods for e-payment. *Decis Support Syst.* (2018) 106:1–14. doi: 10.1016/j.dss.2017.11.003
66. Chauhan V, Pathak GS, Yadav R. Intention to adopt internet banking in an emerging economy: a perspective of Indian youth. *Int J Bank Mar.* (2015) 33:530–44. doi: 10.1108/IJBM-06-2014-0075
67. Hoque MR. An empirical study of mHealth adoption in a developing country: the moderating effect of gender concern. *BMC Med Inform Decis Mak.* (2016) 16:51. doi: 10.1186/s12911-016-0289-0
68. Polites GL, Karahanna E. Shackled to the status quo: the inhibiting effects of incumbent system habit, switching costs, and inertia on new system acceptance. *MIS Q.* (2012) 36:21–42. doi: 10.2307/41410404

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The Relationship Between Safety Climate and Performance in Intensive Care Units: The Mediating Role of Managerial Safety Practices and Priority of Safety

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Patient safety is defined as the absence of preventable harm to a patient during the delivery of healthcare. Evidence from several reports and research studies reflect the high incidence and subsequent high cost of patient harm in general and within intensive care units. Against this background, this study tests a theoretical framework addressing relationships among patient safety climate dimensions and their impact on safety performance. The dimensions refer to safety in terms of procedure suitability and information flow, managerial safety practices, and priority of safety. A retrospective cross-sectional analytical research study was conducted. The target population was recruited from the three intensive care units in the main tertiary level hospital in Malta. A sample of 215 healthcare professionals, who fit the eligibility criteria, participated in this research study, achieving a response rate of 82.7%. The “Survey on Patient Safety Climate” was utilized. Findings support the following hypotheses: the higher the extent to which safety procedures are perceived as suitable to the intensive care units’ daily work demands and processes, the lower the intensive care units’ clinical incidents ($r = -0.269$, $p \leq 0.01$) and the higher the extent to which safety information flow is perceived as clear and unambiguous to the intensive care units’ daily work demands and processes, the lower the intensive care units’ clinical incidents ($r = -0.295$, $p \leq 0.01$). Findings also support the following hypotheses: managerial safety practices mediate the relationship between safety procedure suitability/safety information flow and clinical incidents ($p = 0.009$, $p = 0.014$, respectively) and priority of safety mediates the relationship between safety procedure suitability/safety information flow/managerial safety practices and clinical incidents ($p = 0.002$, $p = 0.002$, $p = 0.042$, respectively). Health service managers must ensure employees perceive safety procedures as suitable and safety information as clear and unambiguous, emphasize the manager’s role as a safety referent and safety change agent and create an organization that prioritizes safety over work pace, workload and pressure for production. Essentially, health service managers need to create safety leaders to drive the organization to patient safety.

Keywords: patient safety, safety climate, intensive care unit, safety procedure suitability, safety information flow, managerial safety practices, safety priority, empirical study

INTRODUCTION

The World Health Organization (WHO) (1) defines patient safety as the absence of preventable harm to a patient during the delivery of healthcare. Categories of harm include falls and fractures, procedure related, therapeutic related, diagnostic related, drug related or operation related (2). Estimates show that in developed countries as many as one in ten patients is harmed while receiving hospital care (3). Also, ~40% of all healthcare spending is wasted due to poor quality care, resulting in additional hospitalization, litigation costs, infections acquired in hospitals, disability, lost productivity, and medical expenses. Subsequently, the WHO (3) recognizes patient safety as a serious global public health issue.

Concern over the levels of patient safety within hospitals was raised following a series of research studies, in the United States (US) (4–7) and in the United Kingdom (UK) (8). Events were single cases (for example: wrong site surgery, medication errors) or a number of patients had been killed either by the same errors committed by different professionals (for example: the Vincristine deaths) or by the same doctors making repeated errors (for example: the Manitoba and Bristol pediatric surgery fatalities) (9). Therefore, government agencies responded with a series of influential reports (9). In 1999, the US Institute of Medicine (IOM) and in 2000, the UK Department of Health published landmark reports *To Err is Human: Building a Safer Health System* (10) and *An Organization with a Memory* (11), respectively. More recently, the *Francis Inquiry Report* into the Mid-Staffordshire National Health Service Foundation Trust revealed widespread systemic failings among hospital staff (12, 13). The most alarming statistic is from the IOM report, which showed that between 44,000 and 98,000 people die in US hospitals each year as a result of medical errors at a cost of \$17–\$29 billion (10).

Within Intensive Care Units (ICUs), patient safety is also a problem. Rothschild et al. (14) conducted a prospective multidisciplinary epidemiologic study in the US: the Critical Care Safety Study. A total of 391 patients with 420 unit admissions were studied during 1,490 patient days. Findings indicated a high incidence of adverse events, preventable adverse events and serious errors (80.5, 36.2, 149.7 per 1,000 patient days, respectively). Garrouste-Orgeas et al. (15) conducted a prospective observational multi-center cohort study in France: the IATROREF study. A total of 70 ICUs and 1,369 patients were studied over a 1-week period. Findings also indicated a high incidence of medical errors. One thousand one hundred ninety-two medical errors were reported for 1,369 patients. The most common medical error was an error in insulin administration (185.9 per 1,000 days of insulin). Also, Kaushal et al. (16) conducted a prospective observational study in the US. Findings indicated that for 56 medical ICU patients the cost of an adverse event was \$3,961. This extrapolated to annual costs of \$853,000.

Therefore, this study aimed at developing a better understanding of the relationships among patient safety climate dimensions and their impact on safety performance. This is important to gain better insight on how to manage in non-routine work environments (17) and to shed light on the

fact that managers need to move beyond formal aspects to ensure safety (18). Subsequently, this study examines the significance that employees perceive safety procedures as suitable, safety information flow as clear and unambiguous, managerial practices as emphasizing safety and safety is prioritized over work pace, workload and pressure for production. Also, this study aimed to add to the paucity of research on patient safety carried out in Malta and to provide groundwork for future research.

The main objectives are:

- To develop hypotheses based on theoretical models and findings from selected research studies from healthcare and industry,
- To gather data on healthcare professional's perceptions toward patient safety climate,
- To group the perceptions to reflect the four dimensions of safety climate: safety procedure suitability, safety information flow, managerial safety practices, and priority of safety,
- To test relationships between such dimensions based on the proposed hypotheses,
- To compare the findings to similar research studies carried out internationally and,
- Based on the findings, to identify recommendations for healthcare service management, and future research.

The research questions are:

- To what extent does safety in terms of procedure suitability and information flow predict the occurrence of the ICUs' clinical incidents?
- To what extent and how do managerial safety practices influence the relationships between safety in terms of procedure suitability/information flow and the ICUs' clinical incidents?
- To what extent and how does priority of safety influence the relationships between safety in terms of procedure suitability/information flow/managerial safety practices and the ICUs' clinical incidents?

METHODS

Hypotheses Development

Throughout the years, a plethora of researchers have addressed safety culture, and/or safety climate. Following review, it was evident that at times the terms were used inadvertently interchangeably. Subsequently, for the purposes of this study, the terms were distinctively distinguished.

On the one hand, the term safety culture was first used in the aftermath of the Chernobyl nuclear disaster (19). The accident investigation report by the International Atomic Energy Agency described the accident arising through a poor safety culture at the plant and within the wider Soviet society (20). Therefore, safety culture was defined as “the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of an organization's health and safety management” [(21), p. 23]. Throughout the years, various researchers have

defined safety culture (in industry and healthcare) and examples are listed in **Appendix 1**.

On the other hand, the term safety climate first appeared in an investigation of safety attitudes in Israeli manufacturing by Zohar (22). Safety climate was defined as “a summary of molar perceptions that employees share about their work environments” [(22), p. 96]. Another popular definition of safety climate is that by Schneider (23). Safety climate was defined as “shared perception regarding the events, practices, and procedures, as well as the kind of behaviors that get rewarded, supported, and expected in a particular organizational setting” [(23), p. 384]. Again, throughout the years various researchers have defined safety climate (in industry and healthcare) and examples are listed in **Appendix 2**. Nevertheless, the distinction between culture and climate remains a source of debate and confusion in the safety field (24). Given that organizations are inherently hierarchical in structure, Flin (9) identifies multiple levels at which safety climate can be investigated. Hofmann and Stetzer (25) suggested that such levels include: individual, work groups, departments, organizations, and environments. Furthermore, according to Zohar and Luria (26), safety climate can be described in terms of two parameters: strength of climate (weak to strong) referring to the consensus concerning climate perceptions and level of climate (low to high) referring to the relative priorities of focal facets signified by climate perceptions. Moreover, a number of researchers (27–29) claim safety climate is a unidimensional variable while others (30, 31) claim is a multidimensional variable.

In industry, Griffin and Neal (32) produced and tested one of the first theoretical frameworks illustrating how safety climate relates to safety performance. In their model, the influence of safety climate on safety performance is mediated by worker knowledge, skill, and motivation. Furthermore, Neal and Griffin (33) explained that safety climate influences worker's knowledge and motivation, which in turn impacts on their safety behaviors and ultimately on safety outcomes. Christian et al. (34) built upon Neal and Griffin's (33) model of workplace safety. The researchers posited that situation related factors (safety climate and leadership) and person related factors (personality characteristics and job attitudes) are distally related to safety performance and even more distally related to safety outcomes. These factors are expected to impact more proximal person related factors such as safety motivation and safety knowledge that directly affect safety performance behaviors. Zohar (35) produced and tested a model where workers' behaviors-outcome expectancies mediate the relationship between their climate perceptions and safety behaviors. This is because expectations of how managers (and peers) respond to particular actions (for example: prioritizing safety over production targets) will to a significant extent determine which behaviors are executed. Flin (9) adapted the Griffin and Neal (32) and Zohar (35) models of workplace safety to show both patient and healthcare worker injuries as adverse outcomes. This study builds on the work conducted by Katz-Navon et al. (18) and Naveh et al. (17) and tests a theoretical framework (**Figure 1**) addressing relationships among patient safety climate dimensions and their impact on safety performance.

a) Safety Procedure Suitability

An organization is a complex system that develops a strategy to convert inputs to outputs (36). This process depends on four components: clinical work, people, formal structures and processes, and informal structures and processes (36). Nadler and Tushman (37) developed a simple pragmatic approach to such dynamics, known as congruency theory. This theory suggests that when the four components are aligned (or congruent) internally and with the strategy, the organization can perform effectively and produce quality outcomes. In turn, lack of congruency leads to failure to achieve the organization's targets.

Findings from Katz-Navon et al. (18) and Naveh et al. (17) support the hypothesis that the higher the extent to which procedures are perceived as suitable to the unit's daily work demands and processes, the lower the unit's treatment errors. This is in agreement with findings from Hofmann and Mark (38) and Singer (39) who explored safety climate in terms of its direct effects in healthcare settings addressing specifically patient safety. Findings from Hofmann and Mark (38) support the hypothesis that safety climate (conceptualized as “job duties allow for safe performance,” in conjunction with other safety climate dimensions) was negatively associated to medication errors and urinary tract infections. Also, findings from Singer (39) support the hypothesis that safety climate (conceptualized as “features of the organization,” in conjunction with other safety climate dimensions) was negatively associated with selected Agency for Healthcare Research and Quality's Patient Safety Indicators. This is also in agreement with findings from Mearns et al. (40) who explored safety climate in terms of its direct effects in industry. Findings support the hypothesis that safety climate (conceptualized as “satisfaction with safety activities,” in conjunction with other safety climate dimensions) was negatively associated to employees experiencing accidents and official accident reports.

In line with congruency theory, the following hypothesis is proposed:

1a. The higher the extent to which safety procedures are perceived as suitable to the ICU's daily work demands and processes, the lower the ICU's clinical incidents.

b) Safety Information Flow

However, safety procedure suitability may never cover all possible contingencies in non-routine work (17). Therefore, researchers (17, 18, 41) maintain that the way in which safety procedures are perceived and interpreted by employees is also associated with reduced treatment errors. Katz-Navon et al. (18) hypothesized and tested a curvilinear relationship between safety information flow and treatment errors. However, findings did not support a curvilinear relationship but suggest the possibility of a linear relationship. Despite this, findings from Naveh et al. (17) indicated a positive effect for safety information flow. Therefore, the higher the safety information flow, the higher the number

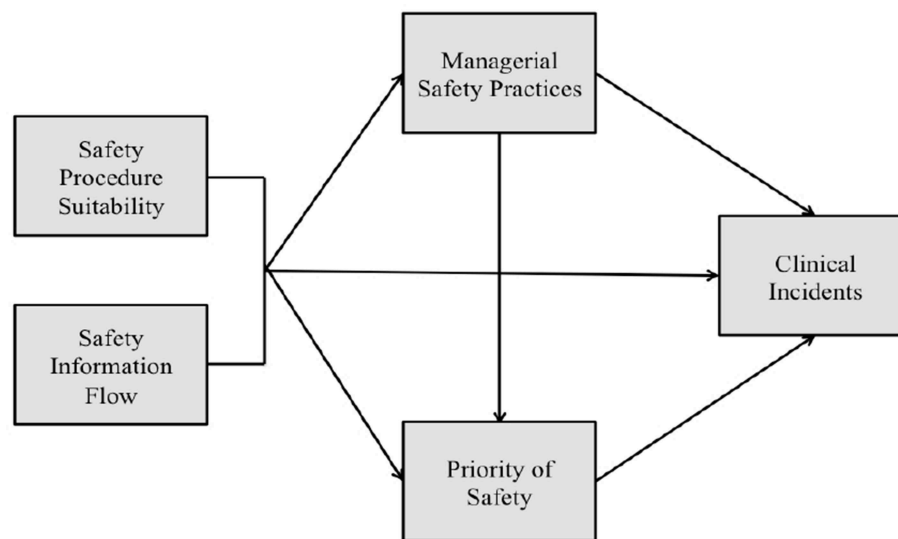


FIGURE 1 | Proposed theoretical framework.

of treatment errors. The researchers did not explain this result. However, this may simply reflect the fact that the higher the level of safety, the more treatment errors are disclosed rather than covered up. On the other hand, findings from Singer (39) in healthcare settings addressing specifically patient safety, support the hypothesis that safety climate (conceptualized as “interpersonal dynamics among individuals,” in conjunction with other safety climate dimensions) was negatively associated with selected patient safety indicators.

In industry, findings from Pousette et al. (42) support the hypothesis that safety climate (conceptualized as “safety communication” in conjunction with other safety climate dimensions) predicted safety behavior in a longitudinal study. Additionally, findings from Hofmann and Stetzer (27) support the hypothesis that group processes and functioning (the interaction that takes place among employees for example, communication, and coordination) is negatively associated with the number of recordable accidents. Also, findings from Mearns et al. (40) support the hypothesis that safety climate (conceptualized as “communication about health and safety,” in conjunction with other safety climate dimensions) was negatively associated with employees experiencing accidents and official accident reports.

In line with congruency theory, the following hypothesis is proposed:

1b. The higher the extent to which safety information flow is perceived as clear and unambiguous to the ICU’s daily work demands and processes, the lower the ICU’s clinical incidents.

c) Managerial Safety Practices

“Learning would be exceedingly laborious not to mention hazardous if people had to rely solely on the effects of their own actions to inform them what to do. Fortunately, most

human behavior is learned observationally through modeling: from observing others, one forms an idea of how new behaviors are performed and on later occasions this coded information serves as a guide for action” [(43), p. 22]. This approach is known as Social Learning Theory and suggests that people learn through observing others’ behaviors, attitudes, and outcomes of those behaviors (43). Therefore, observational learning is governed by four processes; attention, retention, reproduction, and motivation (43).

Managerial safety practices refer to the extent to which employees perceive their manager’s behavior toward safety, which lets employees understand the extent to which the manager is committed to safety (17, 18). Zohar (35) argues that the essential dimension of safety climate is in fact, management commitment to safety and this solely suffices as a measure of safety climate. Zohar (22) indicated that in factories having successful safety programs there was a strong management commitment to safety. In low accident companies top management was personally involved in safety activities on a routine basis, whereas such commitment was conspicuously absent in high accident companies. In agreement with this, Zohar and Luria (26) contend that the most significant information is derived from episodes or occurrences that reveal management safety practices. Such episodes or occurrences serve as climate indicators that reveal the priority of key facets, which may differ from formal declarations (26).

Managerial Safety Practices as a Mediator Variable

Throughout the years, research studies have empirically explored safety climate (conceptualized as solely managerial safety practices or in conjunction with other safety climate dimensions) in terms of its mediating effects on relationships between various variables and safety related outcomes. However, six of the

eight research studies identified, recruited participants from industry whereas two recruited participants from health care, one addressed occupational safety while the other addressed patient safety.

Findings from Zohar (44), McFadden et al. (45), Martinez-Córcoles et al. (46), and Clarke (47) support the hypothesis that safety climate (conceptualized as solely managerial safety practices or in conjunction with other safety climate dimensions) mediated the relationship between leadership style and safety related outcomes. Zohar (44) and Clarke (47) tested both a transformational and transactional leadership style. On other hand, in healthcare addressing specifically patient safety, McFadden et al. (45) simply tested a transformational leadership style. Similarly, Martinez-Córcoles et al. (46) tested a leadership style based on the Empowering Leadership Model. This model identifies five different behaviors empowered leaders must show: leading by example, participative decision making, coaching, informing, and showing concern or interacting with employees.

Despite this, leaders may be transformational in one aspect of the job (achieving high production levels) but passive in other areas (achieving safety standards) (48). Subsequently, transformational leaders are not necessarily safety leaders (48). This is in agreement with findings from Barling et al. (29). Findings support the hypothesis that safety climate (conceptualized as solely managerial safety practices) mediated the relationship between safety specific transformational leadership and occupational injuries. Also, safety climate, safety consciousness, and safety-related events mediated the relationship between safety specific transformational leadership, role overload, and occupational injuries.

Findings from Zacharatos et al. (49) support the hypothesis that safety climate (conceptualized as management values in conjunction with other safety climate dimensions) mediated the relationship between human resource management practices related to high performance work systems and safety performance. Moreover, findings also supported the hypothesis that safety climate and trust in management mediated the relationship between human resources management practices related to high performance work systems and safety incidents. Also, findings from Wallace et al. (50) support the hypothesis that safety climate (conceptualized as solely managerial safety practices) mediated the relationship between management employee relationships and rate of accidents. Additionally, findings also supported the hypothesis that safety climate mediated the relationship between organizational support and rate of accidents.

In line with Social Learning Theory, the following hypotheses are proposed:

- 2a. Management safety practices mediate the relationship between safety procedure suitability and the ICU's clinical incidents.
- 2b. Management safety practices mediate the relationship between safety information flow and the ICU's clinical incidents.

d) Safety Priority

The expectancy theory explains how an employee's behavior is determined by beliefs in three areas: expectancy

(the extent to which increased effort will lead to improved performance), instrumentality (the extent to which improved performance will lead to a specified outcome), and valence (the extent to which that outcome is valued by the individual) (51). Performance is a function of skill and motivation. Skill relates to abilities (innate and acquired through, for example, safety procedures, and/or safety information flow) while motivation comprises the effort expended by the employee and the knowledge of what is expected by others (51). Effort is determined by the value to be derived as a result of the effort and the strength of the link between effort and the rewards. Expectancy theory leads employees to ask questions, such as: If I exert more effort is the safety goal attainable? Will the safety goal be rewarded? How much do I value the reward I will receive? Are alternative goals likely to be rewarded more highly? (52).

Safety priority refers to the extent to which employees' perceive safety as a top priority within the organization (17, 18). In other words, safety priority refers to the extent to which employees prioritize safety against work pace, workload, and pressures for production. Employees may base such priorities on their perception of probable consequences of safe or unsafe behavior (17, 18).

Safety Priority as a Mediator Variable

Throughout the years, research studies have empirically explored safety priority as a mediator that influences the relationship between various variables and safety related outcomes. Griffin and Neal (32) argue that the value that individuals personally place on safety is an individual motivational construct rather than an aspect of safety climate. In view of this, the author included research studies that explored the dimension safety motivation to reflect the dimension safety priority as a mediator that influences the relationship between various variables and safety related outcomes. However, five of the eight research studies identified, recruited participants from industry whereas three recruited from healthcare, one addressed occupational safety, and two addressed patient safety.

In healthcare addressing occupational safety, Neal et al. (28) and in industry, Griffin and Neal (32) hypothesized that safety motivation and safety knowledge would mediate the relationship between safety climate (conceptualized as management values, safety communication, safety training, and safety systems) and safety performance. The researchers' model incorporated two dimensions of safety performance: compliance and participation. Safety compliance refers to core safety behaviors such as employees' adherence to safety rules, regulations, and procedures. Safety participation refers to employees' voluntary engagement or extra effort for safety that goes beyond formal role prescriptions such as participating in a safety committee, helping others with safety matters, or attending a voluntary safety meeting. This differentiation is based on an organizational model of task performance and contextual performance as components of job performance (53). Therefore, compliance activities are generally mandated while participatory activities are generally voluntary. Findings from both research

studies indicated that safety motivation and safety knowledge mediated this relationship.

In a meta-analysis, Christian et al. (34) hypothesized that safety climate would positively influence safety performance (through safety knowledge and motivation) and to negatively influence outcomes. Safety climate was conceptualized as management commitment, human resource management practices, supervisor support, internal group processes, boundary management, risk, and work pressure. Findings indicated that safety knowledge and safety motivation mediated the relationship between safety climate and safety performance. A strong safety climate should encourage safe action either through reward or through principles of social exchange (32, 54, 55). Also, a strong safety climate should enhance safety knowledge due to an environment where safety information is communicated formally through training and informally through on-the-job discussions (34). Furthermore, the researchers hypothesized that safety climate would be more strongly related to safety participation than safety compliance, due to the voluntary nature of participation, and the motivational desire of employees to reciprocate manager actions regarding safety (34).

Also, findings from Clarke (56) indicated that perceived safety climate (safety priority and managerial safety practices) mediated the relationship between dimensions of psychological climate (job, role, group, leader, and organizational attributes) and safety behavior. As previously mentioned, finding from McFadden et al. (45) and Clarke (47) supported the hypothesis that safety climate (conceptualized as safety priority and managerial safety practices) mediated the relationship between leadership style and safety related outcomes. Similarly, findings from Zohar (44) supported the hypothesis that priority of safety mediated the relationship between leadership style and safety climate (conceptualized as managerial safety practices). Additionally, findings from Hofmann and Stetzer (27) supported the hypothesis that the tendency for employees to approach one another regarding safety activities (safety priority) mediated the relationship between group processes and functioning (the interaction that takes place among employees for example, communication and co-ordination; information flow) and safety related behavior.

In healthcare addressing patient safety, Naveh et al. (17) contend that, in addition to specific guidance on how to assure safety, safety procedure suitability, and safety information flow send a message about priority of safety. Additionally, the researchers argue that this has a significant role influencing treatment errors (17). Findings support the hypothesis that priority of safety mediated the relationship between safety procedure suitability and treatment errors. Furthermore, that priority of safety mediated the relationship between safety information flow and treatment errors.

In line with expectancy theory, the following hypotheses are proposed:

- 3a. Priority of safety mediates the relationship between safety procedure suitability and the ICU's clinical incidents.
- 3b. Priority of safety mediates the relationship between safety information flow and ICU's clinical incidents.

As previously discussed, Zohar (22) indicated that in factories having successful safety programs there was a strong management commitment to safety. In low accident companies, this commitment was also exhibited when safety matters were given high priority in company meetings and production scheduling based on the conviction that safety is integral part of production systems and accidents are faults in the system. In view of this, the author maintained that managerial safety practices would send a message about priority of safety and this, in turn, would have a significant role influencing treatment errors.

In line with expectancy theory, the following hypothesis is further proposed:

- 3c. Priority of safety mediates the relationship between managerial safety practices and ICU's clinical incidents.

Participants and Procedures

This study is a retrospective cross-sectional descriptive and analytical survey. The target population was recruited from the three ICUs in the main tertiary level hospital in Malta: the Intensive Therapy Unit (ITU), the Cardiac Intensive Care Unit (CICU), and the Neonatal Pediatric Intensive Care (NPICU). Inclusion criteria included all full and part-time healthcare professionals (HCPs) working in the previously mentioned ICUs. HCPs include all staff directly involved in patient care and have been working for at least 1 month in the ICU prior to the investigation. HCPs included charge nurses/midwives, practice nurses/midwives, deputy charge nurses/midwives, senior staff nurses/midwives, staff nurses/midwives, consultants, specialist registrars, higher/basic specialist trainees, and physiotherapists. HCPs on maternity or emigration leave were also contacted. A consecutive sample of HCPs who fit the eligibility criteria were asked to participate. Given that this sample reflected the total population of HCPs working within Maltese ICUs, a sample size calculation was not required.

Measures

Data were collected through a structured self-administered questionnaire. The "Survey on Patient Safety Climate" was adopted from Naveh et al. (17). Permission to use the tool was sought and granted from Naveh et al. (17). Given that all HCPs either read their undergraduate course in English or were required to be fluent in English to work in Malta, it was deemed unnecessary to translate the questionnaire to Maltese. It was assumed that the English language allowed a good expression of ideas and experiences and prevented language barriers (57). The questionnaire was divided into seven sections: safety information flow, safety procedure suitability, priority of safety, managerial safety practices, clinical incidents observed, background information, and additional comments.

The dimension, safety procedure suitability, was assessed with five items statements originally adapted from Brusson and Jacobsson (58) while safety information flow, was also assessed with five items statements originally adapted from Hofmann and Stetzer (27) and O'Reilly (59). On the other hand, managerial safety practices were assessed with eight items originally adapted from Hofmann and Stetzer (27) and Zohar (54) while priority

of safety was assessed with seven items adapted from Zohar (54). Item statements pertaining to each dimension are listed in **Table 1**.

Also, HCPs reported observed clinical incidents over the past 12 months. Four groups of clinical incidents were presented. These included equipment related, such as equipment failure; clinical practice related, such as infection control incidents; pharmaceutical related, such as the administration of the incorrect drug; and administration related, such as delays in patient admission or discharge. The categories of clinical incidents were adopted from Welters et al. (60).

The “Survey on Patient Safety Climate” is a psychometric validated tool having been tested for, face validity, content validity, construct validity, and internal consistency. Naveh et al. (17) did not present evidence of face or content validity. However,

the researchers did perform exploratory and confirmatory factor analysis supporting an acceptable degree of construct validity. On the other hand, the author achieved an acceptable degree of face validity through the pilot study. A charge nurse, a deputy charge nurse, a senior staff nurse, a midwife, a consultant, and a physiotherapist who fit the eligibility criteria were asked to complete the questionnaire. Questions and queries were raised and discussed. No modifications were made to the “Survey on Patient Safety Climate” (Sections A–D). However, with regards to Section E titled “Clinical Incidents Observed” the option “non-applicable” was added. Such a modification was deemed necessary as, for example, physiotherapists do not administer pharmaceutical treatment, and are not able to report the perceived pharmaceutical related treatment errors over the past 12 months. With regards to Section F: question 6, the options charge nurse/midwife, deputy charge nurse/midwife and practice nurse/ midwife were grouped as charge/deputy charge or practice nurse/ midwife. Similarly, the options Postgraduate Diploma, Masters of Science and Doctor of Philosophy were grouped as postgraduate degrees. Such modifications were deemed necessary to ensure anonymity. The author also achieved an acceptable degree of content validity when a member of Patient Safety and Quality Improvement Team (expert on safety) expressed favorable feedback when asked to review the questionnaire. Also, Naveh et al. (17) and the author derived the coefficient alpha. The coefficient alphas (derived by the author) ranged from 0.847 to 0.867. Given that this is above 0.7, the instrument was deemed reliable as maintained by Nunnally (61).

Permission was sought and granted from the University of Malta Research Ethics Committee prior to data collection. Following ethical approval, permission from the Chief Executive Officer, Data Protection Officer, Director of Nursing and Midwifery Services, Chairman of the Anesthesia Department and the Intensive Care Unit Charge Nurses/Midwives was sought and granted. The participant letter clearly stated that completion and return of the questionnaire indicated willingness to participate and, subsequently a written informed consent was not provided.

Data Analysis

The data collected was inputted into the Statistical Package for the Social Sciences (IBM, SPSS) Version 23. For the purpose of this analysis, the scale pertaining to priority of safety was reversed as recommended by Naveh et al. (17). Given that in Malta there are only three ICUs, it was not feasible to analyze data at the work group level. Subsequently, relationships were tested at the individual level only. This was deemed appropriate as all three ICUs provide Level 2 (high dependency) and/or Level 3 (intensive care) care as defined by the Intensive Care Society document Levels of Critical Care for Adult Patients (62). Also, as specified by Luria (63), in order to understand the role of work group level and organizational level practices promoting safety behavior, it is necessary to start with the individual psychological processes of employees.

a) Correlation Analyses

At the individual level, the relationships between safety procedure suitability and clinical incidents observed (1a) and

TABLE 1 | Item statements pertaining to each dimension.

SAFETY PROCEDURE SUITABILITY

- Safety rules and regulations are suitable for the daily activities of the unit
- There are written safety rules and regulations
- The safety rules and regulations relate to all work-related issues
- The safety rules and regulations are detailed enough
- The safety rules and regulations are practical

SAFETY INFORMATION FLOW

- There is a routine process of updating safety rules and regulations
- Employees are informed about potential hazards
- There are safety-training programmes
- Information about safety is distributed regularly
- Safety rules and regulations are presented in a simple and understandable format

MANAGERIAL SAFETY PRACTICES

- My supervisor praises us whenever he sees a job done according to the safety rules
- My supervisor approaches team members during work to draw their attention to safety issues
- My supervisor's attention is drawn to a worker who has violated a safety rule
- My supervisor is committed to adherence to safety rules and procedures
- My supervisor considers safety performance when evaluating performance and in promotion considerations
- My supervisor gets annoyed with workers who ignore safety rules and regulations
- My supervisor ensures there are no hazards in the department that can be harmful to staff health
- My supervisor creates an atmosphere in which people can say whatever they think

PRIORITY OF SAFETY

- In order to get the work done, one must ignore some safety aspects
- Whenever pressure builds up, the preference is to do the job as fast as possible even if that means less safety
- Human resource shortages undermine safety standards
- Safety rules and procedures are ignored
- Safety rules and procedures are nothing more than a cover-up in case of lawsuits
- Ignoring safety is acceptable
- It doesn't matter how the work is done as long as there are no accidents

safety information flow and clinical incidents observed (1b) were investigated using Pearson product-moment correlation coefficient (r). Standard multiple linear regression was performed to identify the best predictor (safety procedure suitability or safety information flow) of clinical incidents observed (64). The F -test was utilized to assess whether the set of independent variables collectively predicted the dependent variable while R -squared, the multiple correlation coefficient of determination, was utilized to determine how much variance in the dependent variable can be accounted for by the set of independent variables (65). The t -test was utilized to determine the significance of each predictor while standardized coefficients beta were used to determine the extent of prediction for each independent variable (65).

b) Mediation Analyses

At the individual level, the relationships between safety procedure suitability and clinical incidents observed mediated by managerial safety practices (2a) and safety information flow and clinical incidents observed mediated by managerial safety practices (2b) were tested. Also, at the individual level, the relationships between safety procedure suitability and clinical incidents observed mediated by priority of safety (3a), safety information flow and clinical incidents observed mediated by priority of safety (3b) and managerial safety practices and clinical incidents observed mediated by priority of safety (3c) were also tested. As illustrated in **Figure 2**, X is causing the mediator M and M is causing Y .

To test such hypotheses, while the Baron and Kenny (66) approach was consulted, Guillaume (67) maintains that the Baron and Kenny (66) approach does not quantify the indirect effect but infers mediation from a set of hypothesis tests and is prone to Type II error (not detecting an effect when there is one). In view of this, the PROCESS macro approach was conducted, Model 4 was utilized [Simple Mediation Model; (68)] and bootstrapping was employed (67).

A series of regression models were fitted:

- I. First, the mediator variable was predicted using the independent variables (A-path);
- II. Then, the dependent variable was predicted using both the independent variables (C') and the mediator (B-path);

III. Finally, the dependent variable was predicted using the independent variables in the absence of the mediator variable (C -path). Therefore, the coefficient beta for A-path, B-path, C' and C -path, and the corresponding p -values were derived.

A measure for the indirect effect of X on Y was presented after the regression model. Therefore, the effect size was reported including limits of the 95% confidence intervals. Mediation occurred when the regression analysis of the independent variable on the dependent variable, controlling for the mediator, was statistically insignificant (67). On the other hand, mediation still occurred when the regression analysis of the independent variable on the dependent variable, controlling for the mediator, is still statistically significant. Some of the effect of the independent variable on the dependent variable would be through the mediator, but there would also be some direct effect (67). Subsequently, the coefficient beta for C' will be less than the coefficient beta for C -path. In view of this, the p -values of the coefficient beta for C' were reviewed. The Sobel's test was conducted to determine the significance of the indirect effect (69). Therefore, the z -values and the corresponding p -values were also derived.

RESULTS

Response Rate, Demographic Data and Mean Scores Pertaining to Each Dimension

A response rate of 82.7% was achieved (215/260). 58% of respondents worked in ITU, 32% in NPICU and 10% in CICU. 66.1% were female while 33.9% were male. 70.2% were between 30 and 49 years old, 20.9% were between 18 and 29 years old while only 8.8% were older than 50 years. 44.2% had between 6 and 15 years of experience, 35.8% had between 1 and 5 years of experience, 10.2% had over 15 years of experience while 9.8% had more than 1 month experience but <1 year experience. 86% of respondents worked full-time while 11.6% worked reduced and 2.3% worked part-time. 55.3% of respondents were staff nurses/midwives, 12.1% were specialist registrars, 10.2% were senior staff nurses/midwives, 7.4% were higher specialist trainees, 6.5% were charge nurses/midwives, deputy charge nurses/midwives or practices nurses/midwives, 4.7% were consultants while 1.9% were senior physiotherapists and also 1.9% were basic specialist trainees. Lastly, 55.3% of respondents hold an undergraduate degree while 23.3% hold a postgraduate degree and 21.4% hold a diploma. The mean scores pertaining to each safety climate dimension were as follows: safety procedure suitability: 14.8 (possible range 5–25), safety information flow: 14.3 (possible range 5–25), managerial safety practices: 26.31 (possible range 8–40), and priority of safety: 24.78 (possible range 7–35).

Correlation Analyses

Findings from correlation analyses (**Table 2**) indicated a small negative correlation between safety procedure suitability and clinical incidents observed ($r = -0.269$, $p \leq 0.01$), with high levels of safety procedure suitability associated with lower levels of clinical incidents observed. Additionally, findings indicated a

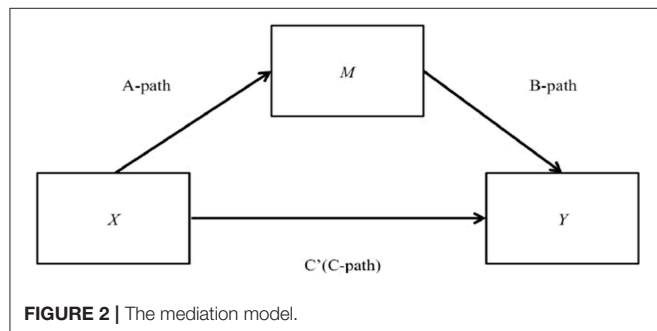


TABLE 2 | The correlation matrix (** $p \leq 0.01$, * $p \leq 0.05$).

	1	2	3	4
1. Safety information flow				
2. Safety procedure suitability	0.694**			
3. Managerial safety practices	0.519**	0.551**		
4. Priority of safety	0.398**	0.475**	0.489**	
5. Clinical incidents	-0.295**	-0.269**	-0.294**	-0.321**

TABLE 3 | Findings from standard multiple linear regression (** $p \leq 0.001$; * $p \leq 0.05$).

	<i>F</i> -test	<i>R</i> ²	Safety procedure suitability		Safety information flow	
			<i>t</i>	<i>b</i>	<i>t</i>	<i>b</i>
Clinical incidents	11.148**	0.095	-1.356	-0.123	-2.316*	-0.210*

small negative correlation between safety information flow and clinical incidents observed ($r = -0.295$, $p \leq 0.01$), with high levels of perceived safety information flow associated with lower levels of clinical incidents observed.

Findings from standard multiple linear regression (Table 3) indicated that safety procedure suitability and safety information flow collectively predicted clinical incidents observed (F -test = 11.148, $p \leq 0.001$). In the regression model, only safety information flow significantly predicted clinical incidents observed (safety procedure suitability $t = -1.356$, $p = 0.177$ vs. safety information flow $t = -2.316$, $p \leq 0.05$).

Mediation Analyses

Findings from mediation analyses (Table 4) indicated that managerial safety practices mediate the relationship between safety procedure suitability/safety information flow and clinical incidents observed ($p = 0.009$, 0.014, respectively). Also, findings indicated that priority of safety mediates the relationship between safety procedure suitability/safety information flow/managerial safety practice and clinical incidents observed ($p = 0.002$, 0.002, 0.042, respectively).

Therefore, findings support the theoretical framework addressing relationships among patient safety climate dimensions and their impact on clinical incidents in Maltese ICUs. The tested theoretical framework is portrayed in Figure 3.

DISCUSSION

Safety Procedure Suitability and Safety Information Flow

Within Maltese ICUs, findings indicated that to a moderate extent, employees perceived safety rules and regulations suitable for the daily activities of the unit, available as written policies or procedures, relevant to the work, detailed enough, and practical (17). Also, to a moderate extent employees perceived safety rules and regulations are updated regularly and presented in a simple

TABLE 4 | Findings from mediation analyses.

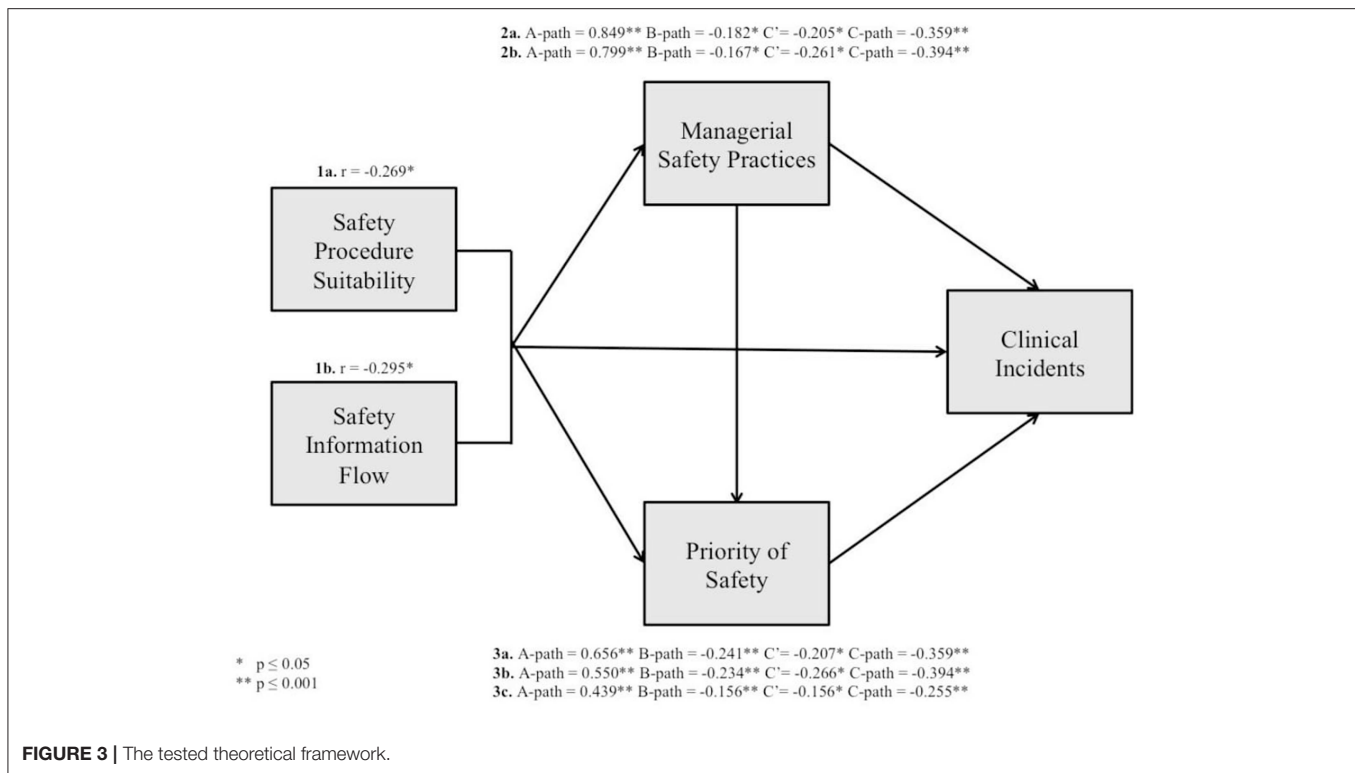
	A-path	B-path	C'	C-path	Indirect effect	CI (indirect effect)	Sobel (z)	<i>p</i> -value
1.	0.849	-0.1815	-0.205	-0.359	-0.154	-0.572 to -0.009	-2.590	0.009
2.	0.799	-0.167	-0.261	-0.394	-0.133	-0.277 to -0.005	-2.447	0.014
3.	0.656	-0.241	-0.207	-0.359	-0.159	-0.262 to -0.074	3.134	0.002
4.	0.550	-0.234	-0.266	-0.394	-0.129	-0.223 to -0.060	3.046	0.002
5.	0.439	-0.156	-0.156	-0.255	-0.099	-0.163 to -0.502	-0.793	0.042

1. The indirect effect of safety procedure suitability on clinical incidents through the mediator, managerial safety practices.
2. The indirect effect of safety information flow on clinical incidents through the mediator, managerial safety practices.
3. The indirect effect of safety procedure suitability on clinical incidents through the mediator, priority of safety.
4. The indirect effect of safety information flow on clinical incidents through the mediator, priority of safety.
5. The indirect effect of managerial safety practices on clinical incidents observed through the priority of safety.

and understandable format. Additionally, to a moderate extent employees felt that they are informed about potential hazards, safety-training programs are available while information about safety is distributed regularly (17).

In agreement with previously mentioned research studies, findings indicated a small negative correlation between safety procedure suitability/safety information flow and clinical incidents observed ($r = -0.269$, $p \leq 0.01$; $r = -0.295$, $p \leq 0.01$, respectively), with high levels of safety procedure suitability/safety information flow associated with lower levels of clinical incidents observed. According to Goodwin and Leech (70), a number of factors may have possibly affected the size of the correlation. Factors include: the amount of variability in either variable, differences in the shapes of the two distributions, lack of linearity in the relationship, the presence of one or more "outliers" in the dataset, characteristics of the sample used and measurement error. Despite this, it is important to note that the correlations were strongly statistically significant.

Findings from standard multiple linear regression, indicated that safety procedure suitability, and safety information flow collectively predicted clinical incidents observed (F -test = 11.148, $p \leq 0.001$). However, in the regression model, only safety information flow significantly predicted clinical incidents observed (safety procedure suitability $t = -1.356$, $p = 0.177$ vs. safety information flow $t = -2.316$, $p \leq 0.05$). These findings may possibly reflect the large correlation between safety procedure suitability and safety information flow ($r = 0.694$, $p \leq 0.01$). Therefore, the variables are said to be collinear (71). Collinearity may cause problems in fitting and interpreting regression models, because the inclusion of two highly correlated variables in a regression model may give the impression that neither is associated with the outcome, even when each exposure is associated (individually) with the outcome (71).



Findings support congruency theory. Within an intensive care setting, findings from Pronovost et al. (72) indicated that the implementation of the central venous catheter (CVC) care bundle resulted in a large reduction of CVC infections (up to 66%) during the 18-months study period. However, findings from this study indicated that it is not simply the implementation of safety procedures that results in safety performance but it is the fact that employees deem safety procedures as suitable and subsequently comply with safety procedures. This is supported by findings from Resar et al. (73), which indicated that ICUs with the highest level of bundle compliance had the highest rate of infection reduction. Findings from this study also indicated that safety procedures must be accompanied by safety information flow, which is deemed clear and unambiguous. This is supported by evidence from Hawe et al. (74) who, designed and implemented a ventilator-associated pneumonia (VAP) prevention bundle in a medical and surgical ICU. The bundle was implemented, first passively then actively. Active implementation involved education, feedback of process and outcome measurements amongst other interventions. Subsequently, the active (rather than passive) implementation was associated with a significant improvement in VAP bundle compliance and decreased incidence of VAP.

Managerial Safety Practices

Within Maltese ICUs, employees perceived that managers in their unit occasionally gave praise when s/he saw a job done according to safety rules, occasionally approached employees during work to draw attention to safety issues and occasionally

approached employees who violate safety rules (17). Employees also perceived that managers in their unit occasionally committed to adhering to safety rules and procedures while occasionally considered safety when evaluating performance and/or in promotion considerations (17). Employees also perceived that managers in their unit occasionally got annoyed with workers who ignored safety rules and regulations and occasionally created an atmosphere in which people can say whatever they think (17).

In agreement with previously mentioned research studies, findings support the hypotheses that managerial safety practices mediate the relationship between safety procedure suitability/safety information flow and clinical incidents observed global ($p = 0.009$, $p = 0.014$, respectively). Findings support social learning theory. Such findings reflect the fact that when employees deem safety procedures as suitable and safety information flow as clear and unambiguous, managers receive messages that safety is important within the unit. This translates to managers' practices that emphasize safety. Therefore, the more employees perceive managerial safety practices as high, the more employees will learn about safety behavior (compliance and participation), and consequently less clinical incidents will occur. This is because managerial behavior provides cues regarding workplace norms and which kind of behavior is likely to be supported, valued or rewarded (75).

Interestingly, Zohar and Polachek (41) distinguish between sent and received role expectations and highlight the fact that this distinction is especially important when such expectations relate to priorities associated with competing role facets (41). Subsequently, when conflict arises between priority of safety

and pressure for production, employees look at their managers for cues to guide their safety behavior (75). The assessment of priorities requires an interpretive sense making process on behalf of employees stemming largely from the difficulty of untangling and discriminating between espoused and enacted priorities (41). Espoused priorities refer to formal organizational safety policies by upper management while enacted priorities refer to the actual implementation and execution of safety procedures among employees (76). Therefore, employee perceptions essentially depend on received role expectations from enacted priorities rather than sent role expectation from espoused priorities (41). In addition to this, Zohar and Polachek (41) also emphasize the fact that changes in the content of received role expectations must remain stable and consistent offering sufficient opportunities for employees to experience and validate it as a real (rather than espoused) change (41). Changes in the content of received role expectations must be experienced in routine and daily leader-member exchanges rather than reserved to formal occasions, offering multiple opportunities for testing managerial enactment of espoused priorities (41). Consequently, a change of safety climate requires repetitive evidence indicative of sustained managerial prioritization of safe performance in the context of daily events or work situations presenting competing operational demands and it is this stability, which implicates genuine commitment to safety (41).

Priority of Safety

Within Maltese ICUs, employees perceived that occasionally in order to get the work done, one must ignore some safety aspects, and whenever pressure builds up, the preference is to do the job as fast as possible even if it means less safety (17). Furthermore, employees perceived that occasionally human resource shortages undermine safety standards and occasionally safety rules and procedures are nothing more than a cover-up of lawsuits (17). Also, employees perceived that occasionally safety rules and procedures are ignored and occasionally ignoring safety is acceptable (17). In addition to this, employees perceived that occasionally it does not matter how the work is done as long as there are no accidents (17).

In agreement with previously mentioned research studies, findings support the hypotheses that priority of safety mediates the relationship between safety procedure suitability/safety information flow/managerial safety practices and clinical incidents observed ($p = 0.002$, $p = 0.002$, $p = 0.042$, respectively). Findings support expectancy theory. Findings reflect the fact that safety procedure suitability/safety information flow/managerial safety practices influence the priority of safety within the organization. Therefore, according to Naveh et al. (17), when safety procedures are deemed unsuitable employees deem priority of safety low within the unit. This is because complying with such procedures requires extra time and effort at the expense of speed and productivity. Subsequently, this situation calls for a trade-off between safety and productivity. Furthermore, according to Naveh et al. (17) an organization, which invests in safety training sessions and safety information distribution, sends the message to employees that not only productivity is important but that safety is also a central issue. Subsequently,

employees should invest time and effort to maintain safety. Also, according to Naveh et al. (17), managers set the tone and tempo for the priority of safety by emphasizing specific safety behaviors and undermining others, by enforcing safety and by recognizing employee safety behavior.

Under What Circumstances Are Managerial Safety Practices and Priority of Safety Critical for Safety Performance?

It is not only important to understand why managerial safety practices and priority of safety are critical for safety performance, but also under what circumstances are they critical for safety performance. Findings from Katz Navon et al. (18) and Bosak et al. (75) indicated that when priority of safety was high the impact of managerial commitment to safety on treatment errors or employees' risk behavior was nullified. Findings from Katz Navon et al. (18) indicated that employees received enough cues regarding the importance of safety within their unit via their understanding of priority of safety. However, Bosak et al. (75) found this effect only for conditions where employees experienced low levels of pressure for production. However, under conditions where employees experienced high levels of pressure for production, management commitment to safety was influential regardless of high vs. low priority of safety. Therefore, when conflict exists between pressure for production and priority of safety employees look at their manager for cues to guide their safety behavior. As managers have a direct bearing on the jobs and allocated rewards of employees, the likelihood of employees to engage in risk behavior is reduced when their manager is highly committed to safety despite a high demand for work place productivity.

Interestingly, findings from Hofmann and Stetzer (25) supported the hypothesis that role overload (pressure for production) was positively associated with the tendency to engage in unsafe acts (for example, adopting "short-cuts"). Also, findings from Hofmann and Mark (38) supported the hypothesis that patient complexity (pressure for production) moderated the relationship between safety climate (conceptualized as job duties allow for safe performance, social standing, management's attitude toward safety) and nurse back injuries and medication errors. In fact, the *Francis Inquiry Report* into the Mid-Staffordshire National Health Service Foundation Trust highlights the impact of staffing cuts on patient care (13). Inadequate staffing levels and staff workload (increased pressure for production) have been identified as key variables determining outcomes such as hospital mortality rates (77) and prolonged length of stay (78).

Strengths and Limitations

This study adds value to patient safety literature. First, because the author did not simply measure the level of safety climate but approached the topic analytically. Second, because the author reviewed literature from various industries (for example metal processing plants, the food and beverage industry, the shipping industry) so as to gain "valuable insight about how to begin the process of improving the safety of healthcare" as advised by the

IOM report [(10), p. 159]. Third, findings are representative of Maltese ICUs because the sample included the total population of HCPs working within Maltese ICUs and achieved a high response rate. However, given that this study included ICUs from Malta only, the ability to extrapolate findings is limited. Other limitations must be given due consideration. First, a cross sectional design was adopted and therefore it is difficult to differentiate between cause and effect from simple association (79). Also, reverse causality cannot be ruled out (42, 80). Second, given that throughout the years different researchers have conceptualized safety climate differently (44), the theoretical framework hypothesized and tested may be more complex. Third, a test-retest reliability procedure was not conducted to establish the stability of the tool. This is important as findings are at risk of acquiescence response bias, mood bias, non-response bias, social desirability bias as well as recall bias (81).

Recommendations

Based on findings, health service managers are recommended to ensure employees perceive safety procedures as suitable and safety information as clear and unambiguous. This may be achieved by, for example, regularly assessing employees perceptions, regularly updating safety procedures in line with up-to-date evidence, encouraging discourse about safety, and/or using technology to improve access to safety information (for example: creating an app to easily access protocols or introducing clinical information systems to facilitate reminders and/or alerts). It is advisable that the managers receive safety training, which emphasizes their role as a safety referent (82), moving beyond safety policy formulation to that of a safety change agent (75). Also, managers are recommended to ensure safety is prioritized over work pace, workload and pressures for production. This may be achieved through the creation of a psychological contract between managers and employees which reflects the fact that safety behavior, is a behavior that is supported, valued, and rewarded (83). Essentially, managers must create good safety leaders who speak of safety, act safely at work, focus on maintaining safety standards, engage others in safety initiatives and recognize individual who adhere to safety (84). Along these lines, good safety leaders must engage in continuous quality improvement such as plan-do-study-act cycles and risk management (85).

Given that the cross-sectional design of this study makes it difficult to conclude whether safety climate is a lagging or leading variable, a longitudinal design is needed to strengthen the ability to infer causality. Future research should also identify and investigate other safety climate dimensions such as pressure for production (75), teamwork (86), non-punitive response of error (87), safety training (44), safety consciousness (29), and safety-specific leadership (48). A qualitative design or even a mixed method approach, such as triangulation may be adopted in an attempt to measure safety culture rather than climate (24, 88, 89). Future research should extend this study to other healthcare settings and analyze data at the work group, rather than at the individual level. However, in order to aggregate data from the individual level, the work group must have a strong safety climate (homogeneity of safety climate perceptions) (9). Essentially,

future research should test a multilevel model of safety climate (31). Future research should investigate safety performance expressed as objective reliable variables such as incidence of ICU-acquired blood stream infections, ICU-acquired pressure ulcers and VAP. Lastly, future research should develop valid and reliable tools measuring safety behavior in terms of patient safety.

CONCLUSION

This study enabled a better understanding of the relationships among patient safety climate dimensions and their impact on safety performance. This is important to gain better insight on how to manage in non-routine work environments (17) and shed light on the fact that managers need to move beyond formal aspects to ensure safety (18). This study emphasized the significance that employees perceive safety procedures as suitable, safety information flow as clear and unambiguous, managerial practices as emphasizing safety and safety is prioritized over work pace, workload, and pressure for production. Conclusively, this study adds value to patient safety literature, providing groundwork for future research.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

Permission was sought and granted from the University of Malta Research Ethics Committee prior to data collection. The participant letter clearly stated that completion and return of the questionnaire indicated willingness to participate and subsequently a written informed consent was not provided.

AUTHOR CONTRIBUTIONS

PT and SB developed the hypotheses and proposed theoretical framework, adopted the Survey on patient safety climate, PT recruited participants, collected data and conducted analysis including correlation and mediation analysis. SB supervised the research. PT, RT, and SB co-wrote the manuscript. All authors approved final manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2019.00302/full#supplementary-material>

REFERENCES

- ## REFERENCES
- World Health Organization. *Patient Safety*. (2016). Available online at: [http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/patient-safety/relax%\\$@\@underlinel\hbox{}{\mathsurround\z@}\\$\relax](http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/patient-safety/relax%$@\@underlinel\hbox{}{\mathsurround\z@}$\relax) (accessed January 10, 2016).
 - de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care*. (2008) 17:216–23. doi: 10.1136/qshc.2007.023622
 - World Health Organization. *10 Facts on Patient Safety*. (2016). Available online at: http://www.who.int/features/factfiles/patient_safety/en/ (accessed January 10, 2016).
 - Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*. (1991) 324:370–6. doi: 10.1056/NEJM199102073240604
 - Leape LL, Brennan TA, Laird NM, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med*. (1991) 324:377–84. doi: 10.1056/NEJM199102073240605
 - Leape LL. Error in medicine. *J Am Med Assoc*. (1994) 272:1851–7. doi: 10.1001/jama.272.23.1851
 - Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, et al. An alternative strategy for studying adverse events in medical care. *Lancet*. (1997) 349:309–13. doi: 10.1016/S0140-6736(96)08268-2
 - Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *Br Med J*. (2001) 322:517–9. doi: 10.1136/bmj.322.7285.517
 - Flin R. Measuring safety culture in health care hospital safety climate: a case for accurate diagnosis. *Saf Sci*. (2007) 45:653–67. doi: 10.1016/j.ssci.2007.04.003
 - Kohn LT, Corrigan JM, Donaldson MS, editors. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academy Press (1999).
 - Department of Health (UK). *An Organization With a Memory*. London: The Stationery Office (2000).
 - Francis RQC. *Independent Inquiry Into Care Provided by Mid Staffordshire NHS Foundation Trust January 2005–March 2009*. London: The Stationery Office (2010).
 - Francis RQC. *The Mid Staffordshire NHS Foundation Trust Public Inquiry*. (2013). Available online at: http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.Midstaffpublicinquiry.com/sites/default/files/uploads/press_releasefinal_report.pdf (accessed April 14, 2014).
 - Rothschild JM, Landrigan CP, Cronin JW, Kaushal R, Lockley SW, Burdick E, et al. The critical care safety study: the incidence and nature of adverse events and serious medical errors in intensive care. *Crit Care Med*. (2005) 33:1694–700. doi: 10.1097/01.CCM.0000171609.91035.BD
 - Garroute-Orgeas M, Timsit JF, Vesin A, Schwebel C, Arnodo P, Lefrant JY, et al. Selected medical errors in the intensive care unit: results of the IATROREF study: parts I and II. *Am J Resp Crit Care Med*. (2010) 181:134–42. doi: 10.1164/rccm.200812-1820OC
 - Kaushal R, Bates DW, Franz C, Soukup JR, Rothschild JM. Costs of adverse events in intensive care units. *Crit Care Med*. (2007) 35:2479–83. doi: 10.1097/01.CCM.0000284510.04248.66
 - Naveh E, Katz-Navon T, Stern Z. Treatment errors in healthcare: a safety climate approach. *Manage Sci*. (2005) 51:948–60. doi: 10.1287/mnsc.1050.0372
 - Katz-Navon TAL, Naveh E, Stern Z. Safety climate in health care organizations: a multidimensional approach. *Acad Manage J*. (2005) 48:1075–89. doi: 10.5465/amj.2005.19573110
 - Poley MJ, van der Starre C, van den Bos A, van Dijk M, Tibboel D. Patient safety culture in a Dutch pediatric surgical intensive care unit: an evaluation using the Safety Attitudes Questionnaire. *Pediatr Crit Care Med*. (2011) 12:e310–6. doi: 10.1097/PCC.0b013e318220afca
 - International Nuclear Safety Advisory Group (INSAG). *Summary Report on the Post-accident Review Meeting on the Chernobyl Accident*. Vienna: International Atomic Energy Agency (1986).
 - Health and Safety Commission (UK). *Organising for Safety: Third Report of the ACSNI (Advisory Committee on the Safety of Nuclear Installations) Study Group on Human Factors*. Sudbury: HSE Books (1993).
 - Zohar D. Safety climate in industrial organizations: theoretical and applied implications. *J Appl Psychol*. (1980) 65:96–101. doi: 10.1037//0021-9010.65.1.96
 - Schneider B. The climate for service: an application of the climate construct. In: Schneider B, editor. *Organizational Climate and Culture*. San Francisco, CA: Jossey-Bass (1990). p. 383–412.
 - Guldenmund FW. The nature of safety culture: a review of theory and research. *Saf Sci*. (2000) 34:215–57. doi: 10.1016/S0925-7535(00)00014-X
 - Hofmann DA, Stetzer A. A cross level investigation of factors influencing unsafe behaviours and accidents. *Pers Psychol*. (1996) 49:307–39. doi: 10.1111/j.1744-6570.1996.tb01802.x
 - Zohar D, Luria G. Climate as a social-cognitive construction of supervisory safety practices: scripts as proxy of behavior patterns. *J Appl Psychol*. (2004) 89:322–33. doi: 10.1037/0021-9010.89.2.322
 - Hofmann DA, Stetzer A. The role of safety climate and communication in accident interpretation: implications for learning from negative events. *Acad Manage J*. (1998) 41:644–57. doi: 10.2307/256962
 - Neal A, Griffin MA, Hart PM. The impact of organizational climate on safety climate and individual behavior. *Saf Sci*. (2000) 34:99–109. doi: 10.1016/S0925-7535(00)00008-4
 - Barling J, Loughlin C, Kelloway EK. Development and test of a model linking safety-specific transformational leadership and occupational safety. *J Appl Psychol*. (2002) 87:488–96. doi: 10.1037//0021-9010.87.3.488
 - Cooper MD, Phillips RA. Exploratory analysis of the safety climate and safety behavior relationship. *J Saf Res*. (2004) 35:497–512. doi: 10.1016/j.jsr.2004.08.004
 - Zohar D, Luria GA. A multilevel model of safety climate: cross-level relationships between organization and group-level climates. *J Appl Psychol*. (2005) 90:616–28. doi: 10.1037/0021-9010.90.4.616
 - Griffin MA, Neal A. Perceptions of safety at work: a framework for linking safety climate to safety performance, knowledge, and motivation. *J Occup Health Psychol*. (2000) 5:34–358. doi: 10.1037//1076-8998.5.3.347
 - Neal A, Griffin MA. Safety climate and safety at work. In: Barling J, Frone MR, editors. *The Psychology of Workplace Safety*. Washington, DC: American Psychological Association (2004). p. 15–34. doi: 10.1037/10662-002
 - Christian MS, Bradley JC, Wallace JC, Burke MJ. Workplace safety: a meta-analysis of the roles of person and situation factors. *J Appl Psychol*. (2009) 94:1103–27. doi: 10.1037/a0016172

35. Zohar D. Safety climate: conceptual and measurement issues. In: Quick JC, Tetrick LE, editors. *Handbook of Occupational Health Psychology*. Washington, DC: American Psychological Association (2003). p. 123–42. doi: 10.1037/10474-006
36. Ramanujam R, Keyser DJ, Sirio CA. Making a case for organizational change in patient safety initiatives. In: Henriksen K, Battles JB, Marks ES, Lewin DI, editors. *Advances in Patient Safety: From Research to Implementation*. Rockville, MD: Agency for Healthcare Research and Quality (2005). p. 455–65.
37. Nadler DA, Tushman ML. Organizational frame bending: principles for managing reorientation. *Acad Manage Exec.* (1989) 3:194–204. doi: 10.5465/ame.1989.4274738
38. Hofmann DA, Mark B. An investigation of the relationship between safety climate and medication errors as well as other nurse and patient outcomes. *Pers Psychol.* (2006) 59:847–69. doi: 10.1111/j.1744-6570.2006.00056.x
39. Singer S, Lin S, Falwell A, Gaba D, Baker L. Relationship of safety climate and safety performance in hospitals. *Health Serv Res.* (2009) 44:399–421. doi: 10.1111/j.1475-6773.2008.00918.x
40. Mearns K, Whitaker SM, Flin R. Safety climate, safety management practice and safety performance in offshore environments. *Saf Sci.* (2003) 41:641–80. doi: 10.1016/S0925-7535(02)00011-5
41. Zohar D, Polachek T. Discourse-based intervention for modifying supervisory communication as leverage for safety climate and performance improvement: a randomized field study. *J Appl Psychol.* (2014) 99:113–24. doi: 10.1037/a0034096
42. Pousette A, Larsson S, Törner M. Safety climate cross-validation, strength and prediction of safety behaviour. *Saf Sci.* (2008) 46:398–404. doi: 10.1016/j.ssci.2007.06.016
43. Bandura A. *Social Learning Theory*. New York, NY: General Learning Press (1977).
44. Zohar D. The effects of leadership dimensions, safety climate, and assigned priorities on minor injuries in work groups. *J Organ Behav.* (2002) 23:75–92. doi: 10.1002/job.130
45. McFadden KL, Henagan SC, Gowen CR. The patient safety chain: transformational leadership's effect on patient safety culture, initiatives, and outcomes. *J Operat Manage.* (2009) 27:390–404. doi: 10.1016/j.jom.2009.01.001
46. Martínez-Córcoles M, Gracia F, Tomás I, Peiró JM. Leadership and employees' perceived safety behaviours in a nuclear power plant: a structural equation model. *Saf Sci.* (2011) 49:1118–29. doi: 10.1016/j.ssci.2011.03.002
47. Clarke S. Safety leadership: a meta-analytic review of transformational and transactional leadership styles as antecedents of safety behaviours. *J Occup Organ Psychol.* (2013) 86:22–49. doi: 10.1111/j.2044-8325.2012.02064.x
48. Mullen JE, Kelloway EK. Safety leadership: a longitudinal study of the effects of transformational leadership on safety outcomes. *J Occup Organ Psychol.* (2009) 82:253–72. doi: 10.1348/096317908X325313
49. Zacharatos A, Barling J, Iverson RD. High-performance work systems and occupational safety. *J Appl Psychol.* (2005) 90:77–93. doi: 10.1037/0021-9010.90.1.77
50. Wallace JC, Popp E, Mondore S. Safety climate as a mediator between foundation climates and occupational accidents: a group-level investigation. *J Appl Psychol.* (2006) 91:681–8. doi: 10.1037/0021-9010.91.3.681
51. De Simone S. Expectancy value theory: motivating healthcare workers. *Am Int J Contemp Res.* (2015) 5:19–23.
52. Lingard H, Rowlinson S. *Occupational Health and Safety in Construction Project Management*. London & New York, NY: Spon Press, Taylor & Francis Group (2005) doi: 10.4324/9780203507919
53. Borman WC, Motowidlo SM. *Expanding the Criterion Domain to Include Elements of Contextual Performance*. San Francisco, CA: Jossey-Bass, Personnel Selection in Organizations (1993).
54. Zohar D. A group-level model of safety climate: testing the effect of group climate on microaccidents in manufacturing jobs. *J Appl Psychol.* (2000) 85:587–94. doi: 10.1037/0021-9010.85.4.587
55. Hofmann DA, Morgeson FP, Gerras SJ. Climate as a moderator of the relationship between leader-member exchange and content specific citizenship: safety climate as an exemplar. *J Appl Psychol.* (2003) 88:170–8. doi: 10.1037/0021-9010.88.1.170
56. Clarke S. An integrative model of safety climate: linking psychological climate and work attitudes to individual safety outcomes using meta-analysis. *J Occup Organ Psychol.* (2010) 83:553–78. doi: 10.1348/096317909X452122
57. Baldacchino DR, Bowman GS, Buhagiar A. Reliability testing of the hospital anxiety and depression. (HAD) scale in the English, Maltese and back-translation versions. *Int J Nurs Studies.* (2002) 39:207–14. doi: 10.1016/S0020-7489(01)00015-3
58. Brunsson N, Jacobsson B. *A World of Standards*. New York, NY: Oxford University Press (2002). doi: 10.1093/acprof:oso/9780199256952.001.0001
59. O'Reilly CA. Individuals and information overload in organizations: is more necessarily better? *Acad Manage J.* (1980) 23:684–96. doi: 10.5465/255556
60. Welters ID, Gibson J, Mogk M, Wenstone R. Major sources of critical incidents in intensive care. *Crit Care.* (2011) 15:1–8. doi: 10.1186/cc10474
61. Nunnally J. *Psychometric Theory, 3rd Edn.* New York, NY: McGraw-Hill (1994).
62. The Faculty of Intensive Care Medicine/The Intensive Care Society. *Core Standards of Intensive Care Units* (2013). Available online at: <http://www.ics.ac.uk/ics-homepage/guidelines-and-standards/> (accessed January 10, 2015).
63. Luria G. Safety climate and supervisory-based interventions. In: Clarke S, Probst TM, Guldenmund F, Passmore J, editors. *The Wiley Blackwell Handbook of the Psychology of Occupational Safety and Workplace Health*. West Sussex, UK: Wiley Blackwell (2016). Chap 16. doi: 10.1002/9781118979013.ch16
64. Pallant J. *SPSS Survival Manual. A Step by Step Guide to Data Analysis Using SPSS, 4th Edn.* Sydney, NSW: Allen & Unwin (2011).
65. Statistics Solutions. *Conduct and Interpret a Multiple Linear Regression* (2013). Available online at: <http://www.statisticssolutions.com/multiple-linear-regression/> (accessed June 1, 2016).
66. Baron RM, Kenny DA. The moderator–mediator variable distinction in social psychological research: conceptual, strategic, and statistical considerations. *J Personal Soc Psychol.* (1986) 51:1173–82. doi: 10.1037/0022-3514.51.6.1173
67. Guillaume Y. *Moderation and Medication Analysis Workshop [Presentation] MSc Health Services Management*. Msida: University of Malta (2014).
68. Hayes AF. *Introduction to Mediation, Moderation, and Conditional Process Analysis: A Regression-based Approach*. New York, NY: Guilford Press (2013).
69. Sobel ME. Asymptotic confidence intervals for indirect effects in structural equation models. In: Leinhard S, editor. *Sociological Methodology*. San Francisco, CA: Jossey-Bass (1982). p. 290–312. doi: 10.2307/270723
70. Goodwin LD, Leech NL. Understanding correlation: factors that affect the size of r. *J Exp Edu.* (2006) 74:249–66. doi: 10.3200/JEXE.74.3.249-266
71. Kirkwood BR, Sterne JA. *Medical Statistics 2nd Edn.* Oxford: Blackwell Science (2003).
72. Pronovost PJ, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med.* (2006) 355:2725–32. doi: 10.1056/NEJMoa061115
73. Resar R, Pronovost P, Haraden C, Simmonds T, Rainey T, Nolan T. Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia. *Joint Commission J Qual Patient Saf.* (2005) 31:243–8. doi: 10.1016/S1553-7250(05)31031-2
74. Hawe CS, Ellis KS, Cairns CJ, Longmate A. Reduction of ventilator-associated pneumonia: active versus passive guideline implementation. *Intens Care Med.* (2009) 35:1180–6. doi: 10.1007/s00134-009-1461-0
75. Bosak J, Coetsee WJ, Cullinane SJ. Safety climate dimensions as predictors for risk behavior. *Accident Anal Prevent.* (2013) 55:256–64. doi: 10.1016/j.aap.2013.02.022
76. Zohar D. The influence of leadership and climate on occupational health and safety. In: Hofman D, Tetrick L, editors. *Health and Safety in Organizations: A Multilevel Perspective*. San Francisco, CA: Jossey-Bass Frontiers Book Series (2003). p. 201–30.
77. Needleman J, Buerhaus P, Mattke S, Stewart M, Zelevinsky K. Nurse-staffing levels and the quality of care in hospitals. *N Engl J Med.* (2002) 346:1715–22. doi: 10.1056/NEJMsa012247
78. Blegen MA, Goode CJ, Spetz J, Vaughn T, Park SH. Nurse staffing effects on patient outcomes: safety-net and non-safety-net hospitals. *Medical Care.* (2011) 49:406–14. doi: 10.1097/MLR.0b013e318202e129

79. Mann CJ. Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emerg Med J.* (2003) 20:54–60. doi: 10.1136/emj.20.1.54
80. Neal A, Griffin MA. A study of the lagged relationships among safety climate, safety motivation, safety behaviour, and accidents at the individual and group levels. *J Appl Psychol.* (2006) 91:946–53. doi: 10.1037/0021-9010.91.4.946
81. Bowling A. *Research Methods in Health. Investigating Health and Health Services, 4th Edn.* New York, NY: Open University Press (2014).
82. Beus JM, Payne SC, Bergman ME, Arthur W Jr. Safety climate and injuries: an examination of theoretical and empirical relationships. *J Appl Psychol.* (2010) 95:713–27. doi: 10.1037/a0019164
83. Mullins LJ. *Management and Organizational Behaviour, 9th Edn.* Essex: Financial Times, Prentice Hall (2010).
84. Wong JHK, Kelloway EK, Makhan DW. Safety leadership. In: Clarke S, Probst TM, Guldenmund F, Passmore J, editors. *The Wiley Blackwell Handbook of the Psychology of Occupational Safety and Workplace Health.* West Sussex: Wiley Blackwell (2016). Chap. 5. doi: 10.1002/9781118979013.ch5
85. Carayon P. *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety.* London, New York, NY: CRC Press, Taylor & Francis Group (2011). doi: 10.1201/b11219-3
86. Sexton JB, Holzmueller CG, Pronovost PJ, Thomas EJ, McFerran S, Nunes J, et al. Variation in caregiver perceptions of teamwork climate in labor and delivery units. *J Perinatol.* (2006) 26:463–70. doi: 10.1038/sj.jp.7211556
87. Sorra JS, Nieva VF. *Hospital Survey on Patient Safety Culture.* Rockville, MD: Agency for Healthcare Research and Quality (2004).
88. Yule S. *Senior management influence on safety performance in the U.K. and U.S. energy sectors.* [doctoral dissertation]. University of Aberdeen, Aberdeen, Scotland (2003).
89. Sexton J, Helmreich R, Neilands T, Rowan K, Vella, K, Boyden J, et al. The safety attitudes questionnaire: psychometric properties, benchmarking data, and emerging research. *BioMed Centr Health Serv Res.* (2006) 6:44. doi: 10.1186/1472-6963-6-44
90. Teuma Custo P. *Patient safety climate in maltese intensive care units.* [dissertation]. Msida: University of Malta (2016).
91. Coyle IR, Sleeman SD, Adams N. Safety climate. *J Saf Res.* (1995) 36:247–54. doi: 10.1016/0022-4375(95)00020-Q
92. Dennis S. Leadership and support for safety. *Nurs Stand.* (2005) 20:52–5. doi: 10.7748/ns2005.11.20.12.52.c4018
93. Lymer UB, Richt B, Isaksson B. Blood exposure: factors promoting healthcare workers' compliance with guidelines in connection with risk. *J Clin Nurs.* (2004) 13:547–54. doi: 10.1111/j.1365-2702.2004.00897.x
94. Wilson KA. *Does safety culture predict clinical outcomes?* [doctoral dissertation]. University of Central Florida, Orlando, Florida (2007).
95. Dedobbeleer N, Béland F. A safety climate measure for construction sites. *J Saf Res.* (1991) 22:97–103. doi: 10.1016/0022-4375(91)90017-P
96. Harvey J, Erdos G, Bolam H, Cox MAA, Kennedy JP, Gregory D. An analysis of safety culture in a highly regulated environment. *Work Stress.* (2002) 16:18–36. doi: 10.1080/02678370110113226
97. Richter A, Koch C. Integration, differentiation and ambiguity in safety cultures. *Saf Sci.* (2004) 42:703–22. doi: 10.1016/j.ssci.2003.12.003
98. National Patient Safety Agency (NPSA). *Seven Steps to Patient Safety: The Full Reference Guide.* London, UK: National Patient Safety Agency (2004).
99. Brown RL, Holmes H. The use of a factor-analytic procedure for assessing the validity of an employee safety climate model. *Accid Anal Prevent.* (1986) 18:455–70. doi: 10.1016/0001-4575(86)90019-9
100. Garavan TN, O'Brien F. the predictors of safety climate: a cross-sectional study. *Irish J Busin Admin Res (IBAR).* (2001) 22:46–57.
101. Kumar S, Simpson AI. Application of risk assessment for violence methods to general adult psychiatry: a selective literature review. *Austr N Zeal J Psychiatry.* (2005) 39:328–35. doi: 10.1111/j.1440-1614.2005.01579.x
102. Goodman GA. Fragmented patient safety concept: the structure and culture of safety management in healthcare. *Hosp Topics.* (2003) 81:22–9. doi: 10.1080/00185860309598018
103. Clarke S. Perception of organizational safety: implications for the development of safety culture. *J Organ Behav.* (1999) 20:185–98. doi: 10.1002/(SICI)1099-1379(199903)20:2<185::AID-JOB892>3.3.CO;2-3
104. Sorensen JN. Safety culture: a survey of the state-of-the-art. *Reliab Eng Syst Saf.* (2002) 76:189–204. doi: 10.1016/S0951-8320(02)00005-4
105. Cox SJ, Cheyne AJT. Assessing safety culture in offshore environments. *Saf Sci.* (2000) 34:111–29. doi: 10.1016/S0925-7535(00)00009-6

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The Impact of the Socio-Demographic Characteristics of Complementary and Alternative Medicine Users in Serbia on OTC Drug Consumption

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The Aim of this research is to analyze how the socio-demographic characteristics of users of Complementary and Alternative Medicine (CAM) in Serbia influence and impact their consumption of OTC drugs. Respondents and methods: The study employed the third edition of the National Health Survey of the Republic of Serbia, published in 2013, as a data source covering the Serbian population. The sample comprised of 550 interviewed individuals who had been applying a variety of CAM treatments over the previous 12 months. Their socio-demographic characteristics were used as independent variables impacting the consumption of OTC drugs over the previous 2-week period, representing the dependent variable.

Results: Two thirds (65.3%) of the CAM users consumed OTC drugs at their own discretion, without recommendation by a physician or a relevant prescription. Users of OTC drugs were most often females whose ages ranged within the average interval of 49.16 ± 16.02 , whose education level was to secondary school diploma, who were married and employed, lived in urban areas, mostly Belgrade, belonged to the middle-income group, and followed relevant headlines via public information channels (TV, the internet, radio, and print). Comparison of the results revealed, on the one hand, that 2/3 of respondents who had used and 1/3 of those who did not consume OTC drugs had undergone fecal occult blood tests over the past year ($p < 0.05$) and, on the other hand, that those respondents had been less frequently hospitalized in the previous year ($p = 0.05$). In addition, the same responders were found to access available health care services more frequently than did others ($p < 0.05$).

Conclusion: Since, according to the statistics, it is highly likely that respondents who were CAM- and OTC drug-users would be less frequently hospitalized and not use medical leave, these results provide a strong indication that this phenomenon

should be investigated in more depth. Moreover, the areas to be considered when defining strategies for determining patient treatments should also include the influence of socio-demographic factors on the patient's consciousness that would enable easier understanding of the proper usage of OTC drugs.

Keywords: CAM, complementary and alternative medicine, OTC drugs, socio-demographic factors, national health survey, health care

INTRODUCTION

Complementary and Alternative Medicine (CAM) has attracted global interest in both developed and underdeveloped countries (1). During the past several decades, post-industrial societies have been characterized to have a “blooming” prevalence and incidence of so-called “prosperity diseases,” i.e., chronic non-infectious diseases. In 2016, the WHO reported that out of 56.9 million deaths worldwide, one-third were caused by ischemic heart disease and stroke. In the past 15 years, cardiovascular diseases have been determined to be the leading cause of death globally (2). Moreover, chronic non-infectious diseases have also been recognized as causing the majority of deaths in Serbia (3). This phenomenon has seriously put to the test the availability and limits of so-called Conventional or Science Medicine. Facing such long-term challenges, in May 2009, the WHO Assembly adopted Resolution 62.13, which calls on all member states and governments to cooperate and share knowledge while simultaneously working on strengthening bonds between conventional and traditional practitioners (4). In most Balkan countries, the introduction of legislation for the development of medicine was interrupted by the civil war that took place in the 90s (5), and this continued through the country's transitional period (6). CAM development also suffered: only in 2007, rather late when compared to other European countries, did the Ministry of Health of the Republic of Serbia enable the introduction of Complementary and Alternative Medicine, to be practiced by health workers only (7).

The abbreviation “OTC” stands for “Over the Counter,” and such drugs are medicines that require no prescription. Research shows that 81% of adults in the USA practice taking OTC drugs as a **first** reaction to a minor health condition (8). A household in the USA, on average, spends about 442 USD on OTC drugs per year (9). As per the results of a systematic review covering 27 studies aiming to calculate the proportion of CAM users within the population of cardiovascular patients, the prevalence of CAM consumption was recorded to be between 22 and 68%; 2–46% consumed herbal medicines, 3–54% consumed vitamins, minerals, and other dietetic supplements (mostly Vitamin B12 or Vitamin B complex, Vitamin C, Vitamin E, Chondroitin Glucosamine, Coenzyme Q10, Calcium, and Magnesium) (10).

Globally, CAM budgets vary significantly, and comparisons are complex firstly due to the different currencies used, secondly because there is no standardization, causing CAM definitions and categorizations to differ, and thirdly because different research time intervals have been used (11). For these reasons, the comparison of OTC use data among populations is complicated.

Based on a National Population-Based Survey in Australia conducted on CAM users, it was noted that 621 million AUD (12) was paid for CAM out-of-pocket in 1993, 1671 million AUD in 2000 (13), 1308 million AUD in 2004 (14), and 1860 million AUD in 2005 (15). In 1990, US citizens spent 10.3 billion USD out of their own pockets (16, 17), in 1997 they spent 34.4 billion USD (18, 19), in 2007, 33.9 billion USD (20, 21), and in 2012, 30.2 billion USD (22). In the UK, a systematic review of studies researching CAM usage prevalence determined that monthly expenses per patient amounted to 15.99 GBP (23). In 1999, the estimated expenses reached 1.6 billion GBP in the UK (24).

The Serbian health care system is funded by both public finances and private contributions (25). About 69% of total current health expenditure is financed by public sources, and more than 90% of public sources are financed through the Republican Health Insurance Fund (26, 27), with supplementary funding from budgetary sources (the Ministry of Finance Fund for the Unemployed, the Pension Fund, etc.) Private funding is completely based on out-of-pocket payments (28), and it is supplemented by contributions from companies that fund their own institutions that specialize in the treatment of occupational diseases and provide primary care services.

The aim of this particular research was to determine which factors impact the usage of OTC drugs among the CAM-using population, or in other words, besides considering health conditions, financial status, lifestyle, the presence of chronic illnesses, and other factors have been included in our observations, as these may contribute to the occurrence of simultaneous usage of CAM and OTC drugs.

MATERIALS AND METHODS

The most recent health research data on the population of the Republic of Serbia were used for this research. It is from a cross-sectional study run by the Ministry of Health of the Republic of Serbia throughout 2013.

In the research, interviews were used, and a horizontal approach was taken, enabling the collection of more personalized data from a single individual (health condition, whether they accessed health care services, habits, and lifestyle). The questions and indicators used in the questionnaires were standardized to those adopted by the European Union, in addition to using indicators standardized to those in the “Health For All” database of the WHO or recommended to become EU indicators (29, 30).

Surveys were conducted as a cross-sectional study. The population presented in the research included adults aged 19 and over. Individuals living in care institutions (elderly care

homes, prisons, and psychiatric institutions) and in Kosovo and Metohija were not included in the research. The research used a national representation sample, which is a stratified two-phase sample without repetition. The sample frame in the research included all the households listed in census to 2011. In order to obtain a random sample, two techniques were used: stratification and multiple-phase sampling. Stratification was conducted in such a way that each of four geographical areas (Vojvodina, Belgrade, Sumadija and west Serbia, and south and east Serbia) represented one main stratum in the sample. Each stratum was divided into cities and other regions. The total number of strata was eight. Two-phase sampling included local communities, selected on the basis of probability proportional to their size, and households as units of the second phase selected on the basis of the linear sampling method with a random start and uniform selection steps. All respondents that had used CAM (acupuncture, homeopathy, phytotherapy/herbal therapy, or chiropractic) over the previous 12 months and were living in the Republic of Serbia were extracted from this database, totaling 550.

Individuals living in care institutions (elderly care homes, prisons, and psychiatric institutions) and in Kosovo and Metohija were not included in the research. The principles of ICH Good Clinical Practice were followed strictly, and approval was obtained from the Ethics Committee of the Republic of Serbia. The research used data from the Third National Health Survey of Serbia, sponsored by the Ministry of Health's Batut Institute, which provided data to the faculty for the purpose of additional research. The Ethical Standards for Healthcare Research are aligned with the International Medical Association Declaration of Helsinki and legislation specific to the laws of Serbia. Aiming to align with GDPR policies to preserve the discretion of the respondent data collected, all steps were adopted that are stipulated by the law on the protection of personal data (Official Gazette of the Republic of Serbia No. 97/08, 104/09), the Official Statistics Law (Official Gazette of the Republic of Serbia No. 104/09), and Directive 95/46/EC of the European Parliament on the protection of individuals with regard to the processing of personal data and on the free movement of such data (31).

Statistical Methods

Continuous variables were presented as mean \pm standard deviation, and categorical variables as frequency (n) and percentage (%). The Chi-square test, representing the univariate method, was used for categorical data, and the Students' *t*-test was used for continuous data. Factor analysis was applied as the multivariate technique. The following variables were analyzed through factor analysis: sex, age, education, region, accommodation, work status, well-being index, health self-evaluation, commitment to being healthy, record of chronic disease, medical leave, hospitalization, visits to day-care hospitals, home medical care and Emergency Room Assistance in the past 12 months, consumption of OTC drugs over the previous 2 weeks, risky behavior, routine checks and screening for colon cancer, and health care non-utilization (communalities higher than 0.2). All analyses were performed using SPSS, version 19.

RESULTS

In Serbia, two-thirds (65.3%) of CAM users consume OTC drugs at their own discretion, neither due to a physician's recommendation nor through prescription. OTC drug consumers are most frequently females with an average age of 49.16 ± 16.02 , possessing a high-school diploma, married and employed, most frequently living in urban areas, mostly Belgrade, categorized as middle-income as per the "wellbeing index," and who follow health topics via publicly available information (TV, the internet, radio, and print).

By comparing the basic socio-demographic characteristics of respondents that consume and that do not consume OTC drugs, it is evident that the consumers are mostly females (Chi-square test = 9.87, *df* = 1, *p* < 0.05) and that OTC consumers are, on average, 4.5 years older than those that do not use OTC drugs (*t* = -3.06, *df* = 548, *p* < 0.05).

There was no statistically significant difference in the use of analgesics with respect to gender, educational attainment, region and place of residence, self-evaluation of health status, presence of chronic health disorders, and long-term illness. On the other hand, individuals falling into the middle-income category more often consume analgesics at their own discretion (Chi-square test = 8.72, *df* = 2, *p* < 0.05), while this practice is rarest among respondents living in the Belgrade region (Chi-square test = 8.68, *df* = 3, *p* < 0.05).

The consumers of OTC drugs mostly evaluate themselves as being in good health, i.e., average, and, even though they are in the habit of risky behavior, have usually never undergone screening tests for colon cancer. Of those respondents, 56% suffer from chronic health disorders and visit health care institutions more frequently than others. Mostly, the users of OTC drugs had not taken any medical leave, been hospitalized, or used day-care hospitals, emergency assistance, or home medical care over the preceding 12 months (Table 1).

Comparison revealed that two-thirds of respondents that had consumed and one-third of those that had not consumed OTC drugs had undergone fecal occult blood tests over the previous year (Chi-square test = 6.37, *df* = 2, *p* < 0.05) and that those respondents had less frequently been hospitalized over the previous 12 months (Chi-square test = 3.67, *df* = 1, *p* = 0.05) (Table 1).

One-third of OTC drug users who were not able to utilize the required healthcare services, which could be due to a number of factors, such as waiting lists, financial insolvency, or perhaps the distance to the required healthcare institution, were employed. Our research, as well as numerous other studies, showed that fear of losing an existing job could be one of the reasons why employed individuals consume OTC drugs (32).

OTC drug users most often rated their own health as good or average, but despite risky behavior, they had generally never undergone screening for colon cancer. Of those respondents, 56% had chronic health disorders and most often utilized the required form of health care. Most OTC users did not take sick leave and had less frequently been hospitalized or used a day hospital,

TABLE 1 | Clinical characteristics and health care practices of participants.

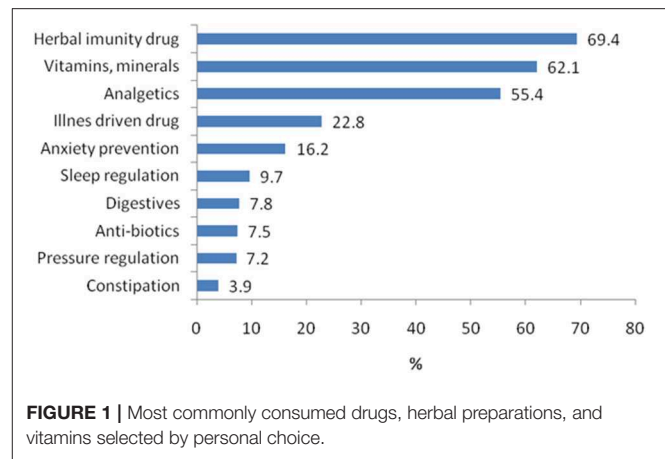
Characteristics	Users OTC n (%)	Non-OTC users n (%)	p-value #
Self-evaluation of health			
Very good	39 (58.2)	28 (41.8)	>0.05
Good	126 (64.3)	70 (35.7)	
Average	130 (69.5)	57 (30.5)	
Bad	49 (63.6)	28 (36.4)	
Very bad	15 (65.2)	8 (34.8)	
Risky behavior			
Yes	187 (67.8)	89 (32.2)	>0.05
No	167 (62.8)	99 (37.2)	
Already ill	5 (62.5)	3 (37.5)	
Fecal occult blood tests			
Over the previous year	16 (69.6)	7 (30.4)	<0.05
More than a year ago	24 (49.0)	25 (51.0)	
Never	317 (66.7)	158 (33.3)	
Colonoscopy			
Over the previous year	8 (66.7)	4 (33.3)	>0.05
More than a year ago	30 (57.7)	22 (42.3)	
Never	320 (66.1)	164 (33.9)	
Chronic disease*			
Yes	202 (66.9)	100 (33.10)	>0.05
No	157 (63.6)	90 (36.4)	
Medical leave*			
Yes	40 (66.7)	20 (33.3)	>0.05
No	92 (63.0)	54 (37.0)	
Hospitalization*			
Yes	41 (55.4)	33 (44.6)	<0.05
No	318 (66.8)	158 (33.2)	
“Day patient” *			
Yes	53 (63.1)	31 (36.9)	>0.05
No	306 (65.7)	160 (34.3)	
Emergency assistance*			
Yes	37 (63.8)	21 (36.2)	>0.05
No	322 (65.4)	170 (34.6)	
Home medical care*			
Yes	7 (53.8)	6 (46.2)	>0.05
No	352 (65.5)	185 (34.5)	
Health care non-utilization			
Yes	162 (70.1)	69 (29.9)	>0.05
No	166 (62.6)	99 (37.4)	

*over previous 12 months; # Chi-square test.

ambulance, or home treatment in the previous 12 months than had others (Table 1).

Most common drugs, herbal supplements, and/or vitamins that the respondents were taking on their own, without prior consultation with a physician, were bought in pharmacies and are presented in Figure 1.

Principal component analysis ($KMO = 0.715$, $p < 0.01$) isolated six factors that explain 53.79% of the variance: Health Condition (17.43% of the variance), Financial Status (10.16% of the variance), Age (7.89% of the variance), OTC Drugs (7.42% of the variance), Risk (6.21% of the variance), and Health Care Utilization (5.94% of the variance).

**FIGURE 1** | Most commonly consumed drugs, herbal preparations, and vitamins selected by personal choice.

The health condition factor groups together the variables health self-evaluation, the existence of chronic disease, and limits to daily activities due to the disease, showing that individuals that suffer from chronic diseases that prevent them from undertaking daily activities evaluate their health as bad. The health condition factor included in the factor analysis also implied the presence of chronic disease (Table 2). There was no statistically significant difference in the use of OTC drugs with respect to the presence of a chronic health disorder, such that 64.4% of those who had and 67.3% of those who did not have a chronic illness used OTC products (Chi-square test = 0.29, $df = 1$, $p > 0.05$).

Similarly to our research, other studies have shown that the use of certain drugs reduces the rate of hospitalization in adults (33). Antiplatelet, diuretic, and non-steroidal anti-inflammatory drugs and anticoagulants are medicines that reduce hospitalization rates (34).

The financial status factor groups five variables: region, accommodation, well-being index, education, and health care non-utilization. This factor shows that individuals living in urban areas in the Vojvodina area, possessing a higher/high degree of education, and classified as very rich as per the well-being index, have never managed to access required health care services due to long waiting lists.

The age factor groups the variables age and employment status and shows that the oldest respondents were retired.

The OTC drugs factor groups four variables: sex, awareness about health topics, OTC drug use, and hospitalization in the previous 12 months. This factor shows that women who were aware of topics related to health and that had consumed OTC drugs over the previous 12 months had not been hospitalized.

The emergency assistance factor, which groups variables related to using emergency assistance in the previous 12 months and risky behavior, showed that already ill patients had been using emergency medical services during the previous 12 months.

The factor explaining health care utilization groups variables such as the selection of a private practice physician and being a day-patient over the previous 12 months. This shows that respondents who had selected a private practice physician

TABLE 2 | Principal component analysis.

Factor (% of variance)	Variables	Factor loading
Health condition (17.43)	Health self-evaluation	−0.759
	Limitations to undertaking daily activities due to illness	0.718
	Chronic disease	0.605
Financial status (10.16)	Accommodation	0.705
	Well-being Index	−0.652
	Education	−0.511
	Region	0.376
	Required visits to health care institutions	0.369
Age (7.89)	Employment	0.546
	Age	0.544
OTC drugs (7.42)	OTC drug use	0.388
	Sex	0.606
	Knowledge about health topics	0.461
	Hospitalization in the previous 12 months	−0.379
	Use of emergency assistance over the previous 12 months	0.428
Emergency (6.21)	Risky behavior	−0.363
	Availability of selected private practice physician	−0.806
Healthcare utilization (5.94)	"Day patient" over the previous 12 months	0.372

were hospitalized fewer times for additional diagnosis/treatment ("Day patient") (Table 2).

- *Analysis of female respondents aware of health topics via public information systems*

The majority of females (71.1%) that followed health topics via public information systems had consumed OTC drugs over the past 2 weeks. Most commonly, they had a high-school diploma. However, 37.2% of females characterized as having a higher/high education level had also used such drugs, while 26.1% of those at the high-school education level had not (Chi-square test = 8.24, $df = 2$, $p < 0.05$). Every third female in the Vojvodina region had consumed OTC drugs over the previous 2 weeks, while every fourth female from the Sumadija and West Serbia regions had not (Chi-square test = 9.02, $df = 3$, $p < 0.05$). OTC drugs had been consumed by 56.7% of females following health topics in addition to having risky behavior. Simultaneously, 39.7%, though well-informed on health issues and acting riskily, had not consumed such drugs (Chi-square test = 6.22, $df = 2$, $p < 0.05$). Further analysis of the female respondents that consumed OTC drugs and followed health-related topics via public information systems (the internet, TV, print, and radio) shows that these respondents had statistically significantly been hospitalized fewer times over the previous year when compared to respondents not using OTC drugs (Chi-square test = 7.98, $df = 1$, $p < 0.05$). Although those female respondents had not accessed any health care services, there was no significant statistical difference in the usage of OTC drugs among respondents following health topics.

- *Analysis of male respondents following health topics via public information systems*

Every second respondent (55.3%) following health topics had consumed OTC drugs over the previous 2-week period. The users of OTC drugs were mostly high-school graduates. No significant statistical difference was found among users of OTC drugs that followed health topics and had different levels of education ($p > 0.05$). OTC drugs were mostly used by males living in the Belgrade region (38.6%) and less so by males from the regions of Sumadija and West Serbia (8.8%) (Chi-square test = 8.13, $df = 3$, $p < 0.05$). No statistically significant difference was found between OTC usage and risky behavior ($p > 0.05$). Among the observed males, no statistically significant difference was found between the use of OTC drugs and hospitalization over the previous 12 months. Of male respondents, 47.8% had neither utilized health care services nor used OTC drugs.

DISCUSSION

In Serbia, as per our local research, two-thirds (65.3%) of CAM users consume OTC drugs at their own discretion, without either a recommendation from a physician or a prescription. These are mostly females of an average age of 49.16 ± 16.02 with a high-school diploma, married and employed, most frequently living in urban areas, mostly Belgrade, classified as of the middle-income class, and following health topics via public information systems (TV, the internet, radio, and print). Most studies that have been undertaken significantly predict that CAM users will be females and interpret this to be the result of their having more frequent communication with their friends and families about their health condition and having been given diagnoses that turned out to be a significant source of information (23, 35–43). However, there are some studies indicating situations where males turned out to be the majority of consumers in cases where they were suffering from, e.g., gout and arthritis (44).

Our data analyses show that the predominant OTC drug users were females with a high-school diploma and also 37.2% of females with a higher/high education diploma, though 19.2% of such females did not use OTC drugs. Globally, the significant predictors in the majority of studies conducted to date point to CAM users being characterized by a high income and vocations requiring a high level of education. The explanation made for this may lie either in the fact that they were financially able to use CAM or in the fact that CAM users are highly educated and hence question the efficiency of conventional medicine (11, 37–40, 42–45). One study that covered Europe pointed out that the variables of being female and having a higher education level are significant socio-demographic characteristics in CAM usage, while other variables varied depending on the CAM type (36).

Worldwide, health condition and health perception, among selected socio-demographic factors, have been found to be significant in making a decision regarding whether an individual would use CAM and OTC, especially when the condition or the individual's perception of their health was described as bad (34, 36, 42). The OTC users in our research mostly perceived their health as good, i.e., average, and though practicing risky behavior, they had almost never undergone Ca colon cancer tests.

Fifty-six percent of these types of respondents suffer from chronic diseases and mostly utilized the required health care services. Worldwide, as per different studies, patients suffering from chronic diseases or some form of disability (35) and other more challenging types of disease (40, 46, 47), decided to use CAM and OTC drugs very frequently due to a lack of expected effects from conventional medicinal treatments or due to the non-availability of a General Practitioner (36). A systematic review of 18 studies in nine countries observing the use of CAM in the diabetic patient population, where prevalence varies from 17 to 72% (average 45%), determined that dietetic supplements, herbal medicines, nutrition consultations, spiritualism, and relaxing techniques were the methods most frequently applied (46). A review of six studies in Saudi Arabia showed the prevalence of CAM use among diabetic patients to be 32.18% and that herbal medicines were most commonly used (47). The most common types of medicines in our research were herbal medicines and/or vitamins that were consumed by the patients on their own, without previous consultation with a physician, and were bought in pharmacies.

In Serbia, according to the Medicines and Medical Devices Act, the advertisement of medicines and medical devices is prohibited, that is, the information that is advertised on a medicinal product or medical device must be true and scientifically proven, cannot mislead the professional and general public, and must be in accordance with the Regulation on the Advertising of Medicines and Medical Devices (48). However, advertising is allowed for OTC drugs. Based on research conducted among students in Poland, we learned that the advertising of OTC drugs is allowed there and is on the rise (49). Interestingly, in both Poland and our research, the largest portion of OTC consumers were females (49). The statistics show that females in Serbia follow health-related topics via the media (TV, the internet, radio, and print), like the females in Poland, but that females were more attentive and less influenced by advertising (49).

Thanks to the research undertaken in Serbia (January 2010–July 2011), pioneering efforts have been made that have resulted in an understanding of the weaknesses in the perceptions of the current and future health workforce toward CAM. It included a questionnaire based on the existing CAM Health Belief Questionnaire (CHBQ), using the Likert scale, where 797 health students and practitioners were interviewed. Students of Dentistry (54.65 ± 6.07) were better informed on CAM therapies than students of Medical Science (50.26 ± 7.92) and students of Pharmacy Science (51.16 ± 7.10). Physicians achieved better results than university professors (55.12 ± 6.55 vs. 50.29 ± 9.50). Furthermore, all of the respondents gave priority to the use of vitamins over any other CAM therapy. In general, consciousness of the use of CAM is increasing in the Balkans (50).

Systematic literature review (42 studies) has found that the prevalence of CAM use ranged from 8 to 90% in patients with prostate cancer (39). A systematic review of four studies on the population of patients with colorectal cancer showed that up to 75% of them used at least one CAM method (51). The most commonly used CAM methods were biologically based therapies: herbal remedies (48.7%), homeopathy (20.5%),

vitamins/minerals (17.9%), medical teas (15.4%), and mind and body medicinal procedures such as spiritual techniques (15.4%) and relaxation techniques (12.8%) (51). According to the results of a systematic review of 49 studies on the use of CAM in patients with arthritis in 12 countries, dietary supplements and massage were the most frequently used (43). For Parkinson's patients, the estimated prevalence of CAM use was found to range from 25.7 to 76%, with the most commonly used CAM methods being massage in the United Kingdom, acupuncture in Sweden and Argentina, vitamins and herbal remedies in the United States, traditional medicine in Singapore, and oriental medicine in South Korea (44).

CONCLUSION

The analysis of socio-demographic factors and their influence on the proper selection of OTC drugs should become a very significant part of the processes conducted in order to define strategies for determining the treatments for particular patients. The research statistics presented here strongly support OTC drugs correlates with an absence of hospitalization, absence of medical leaves, and absence of day-care hospital, emergency assistance, or home medical care usage in the previous 12 months. Furthermore, wider research focusing on the aforementioned factors should enable the improvement of treatment strategies for enhancing patients' well-being.

In addition, although global research indicates growing trends, the actual evidence for the use of CAM methods in Serbia is very poor. In order to enable a comparison of health care service utilization and CAM methods, it would be necessary to take a different approach. This new path would rely on the Ministry of Health of the Republic of Serbia taking a leading role, due to their better understanding of this matter.

DATA AVAILABILITY STATEMENT

Publicly available datasets were analyzed in this study. This data can be found here: https://ec.europa.eu/health/indicators_data/indicators_el; https://ec.europa.eu/health/indicators_data/echi_en; <http://www.healthpowerhouse.com>.

AUTHOR CONTRIBUTIONS

ML-S and MJ jointly designed the study and defined the research questions. NM and NR did most of the data mining and extraction, purification of files for missing data and artifacts, and statistical analysis. NM, NR, and ML-S contributed to table and figure creation and interpretation of data. ML-S, MJ, and NR drafted the working version manuscript. All authors contributed to the final version to the extent of important intellectual content.

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REFERENCES

- Goldbeck-Wood S, Dorozynski A, Lie LG, Yamauchi M, Zinn C, Josefson D, et al. Complementary medicine is booming worldwide. *Br Med J*. (1996) 313:131–3. doi: 10.1136/bmj.313.7050.131
- World Health Organization, Media centre. *Noncommunicable Diseases and Mental Health*. (2019). Available online at: <http://www.who.int/mediacentre/factsheets/fs310/en/index2.html> (accessed June 20, 2019).
- Institute of Public health of Serbia “Dr Milan Jovanovic Batut”. *Statistical Yearbook of the Republic of Serbia 2015*. Belgrade: Institute of Public health of Serbia (2016). Available online at: www.batut.org.rs/download/publikacije/pub2015 (accessed June 20, 2019).
- Robinson MM, Zhang X. *Traditional Medicines: Global Situation, Issues and Challenges. The World Medicines Situation*. 3rd ed. Geneva: WHO (2011). Available online at: http://digicollection.org/hss/documents/_s13e/s1806e3e.pdf (accessed June 20, 2019).
- De Jong JT. A public health framework to translate risk factors related to political violence and war into multi-level preventive interventions. *Soc Sci Med*. (2010) 70:71–9. doi: 10.1016/j.socscimed.2009.09.044
- Petrakos G, Totev S. Economic structure and change in the Balkan region: implications for integration, transition and economic cooperation. *Int J Urban Regional Res*. (2000) 24:95–113. doi: 10.1111/1468-2427.00237
- Cupara S, Djordjevic V, Jakovljevic MB. Current legal status and research on complementary and alternative medicine in Serbia. *J Alter Med Res*. (2013) 5:195.
- Zakonska Regulativa o Farmaceutskoj Delatnosti u Srbiji*. (2019). Available online at: http://www.izjzv.org.rs/app/soc.katedra/Kat_socMed_Zakonska_regulativa_u_farmaceutskoj_delatnosti.pdf
- Consumer Healthcare Products Association. *White Paper: Value of OTC Medicines to the U.S. Healthcare System* (2019). Available online at: <http://overthecounter.org/white-paper/> (accessed June 20, 2019).
- Grant SJ, Bin YS, Kiat H, Chang DH-T. The use of complementary and alternative medicine by people with cardiovascular disease: a systematic review. *BMC Public Health*. (2012) 12:299. doi: 10.1186/1471-2458-12-299
- Pejic AV, Jakovljevic MB. Economic impact of traditional medicine practice worldwide. *Tradit Med Res*. (2017) 2:60–74. doi: 10.12032/TMR201706039
- MacLennan A, Wilson D, Taylor A. Prevalence and cost of alternative medicine in Australia. *Lancet*. (1996) 347:569–73. doi: 10.1016/S0140-6736(96)91271-4
- MacLennan A. The escalating cost and prevalence of alternative medicine. *Prev Med*. (2002) 35:166–73. doi: 10.1006/pmed.2002.1057
- MacLennan AH, Myers SP, Taylor AW. The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004. *Med J Aust*. (2006) 184:27–31. doi: 10.5694/j.1326-5377.2006.tb00092.x
- Xue CC, Zhang AL, Lin V, Da Costa C, Story DF. Complementary and alternative medicine use in Australia: a national population-based survey. *J Altern Complement Med*. (2007) 13:643–50. doi: 10.1089/acm.2006.6355
- Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, Delbanco TL. Unconventional medicine in the United States. Prevalence, costs, and patterns of use. *N Engl J Med*. (1993) 328:246–52. doi: 10.1056/NEJM199301283280406
- Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, Van Rompay M, et al. Trends in alternative medicine use in the United States, 1990–1997: results of a follow-up national survey. *JAMA*. (1998) 280:1569–75. doi: 10.1001/jama.280.18.1569
- Ni H, Simile C, Hardy AM. Utilization of complementary and alternative medicine by United States adults: results from the 1999 national health interview survey. *Med Care*. (2002) 40:353–8. doi: 10.1097/00005650-200204000-00011
- Barnes PM, Powell-Griner E, McFann K, Nahin RL. Complementary and alternative medicine use among adults: United States, 2002. *Adv Data*. (2004) 1–19. doi: 10.1016/j.sigmm.2004.07.003
- Nahin RL, Barnes PM, Stussman BJ, Bloom B. Costs of complementary and alternative medicine (CAM) and frequency of visits to CAM practitioners: United States, 2007. *Natl Health Stat Rep*. (2009) 1–14.
- Barnes PM, Bloom B, Nahin RL. Complementary and alternative medicine use among adults and children: United States, 2007. *Natl Health Stat Rep*. (2008) 1–23. doi: 10.1037/e623942009-001
- Nahin RL, Barnes PM, Stussman BJ. Expenditures on complementary health approaches: United States, 2012. *Natl Health Stat Rep*. (2016) 1–11.
- Posadzki P, Watson LK, Alotaibi A, Ernst E. Prevalence of use of complementary and alternative medicine (CAM) by patients/consumers in the UK: systematic review of surveys. *Clin Med*. (2013) 13:126–31. doi: 10.7861/clinmedicine.13-2-126
- Ernst E, White A. The BBC survey of complementary medicine use in the UK. *Complement Ther Med*. (2000) 8:32–6. doi: 10.1054/ctim.2000.0341
- Arandarenko M, Golcin P. *Serbia. Social Policy and International Interventions in South East Europe*. (2007). 167–86 p.
- The National Health Insurance Fund of the Republic of Serbia*. (2019). Available online at: <https://www.eng.rfzo.rs/index.php/aboutus> (accessed June 20, 2019).
- Vlahovic Z, Radojkovic D. Healthcare in Serbia in transition period. *EPMA J*. (2010) 1:601–6. doi: 10.1007/s13167-010-0055-9
- Vojvodic K, Terzic-Supic Z, Santric-Milicevic M, Wolf GW. Socio-economic inequalities, out-of-pocket payment and consumers' satisfaction with primary health care: data from the national adult consumers' satisfaction survey in Serbia 2009–2015. *Front Pharmacol*. (2017) 8:147. doi: 10.3389/fphar.2017.00147
- World Health Organization. *Databases*. (2019). Available online at: <http://www.euro.who.int/en/data-and-evidence/databases> (accessed June 20, 2019).
- The Health Consumer Powerhouse Ltd. (2019). Available online at: <http://www.healthpowerhouse.com> (accessed June 20, 2019).
- Ilic D, ed. *Results of Serbian Population Health Research 2013*. (2014). Available online at: <http://www.batut.org.rs/download/publikacije/IstrazivanjeZdravljaStanovnistvaRS2013.pdf>
- Alrasheed AA. The impact of waiting time in primary care clinics on self-medication with antibiotics: a hospital based study in Saudi Arabia. *Biomed Res*. (2017) 28:3119–24.
- Bobrovitz N, Heneghan C, Onakpoya I, Fletcher B, Collins D, Tompson A, et al. Medications that reduce emergency hospital admissions: an overview of systematic reviews and prioritisation of treatments. *BMC Med*. (2018) 16:115. doi: 10.1186/s12916-018-1104-9
- Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. *Br J Clin Pharmacol*. (2007) 63:136–47. doi: 10.1111/j.1365-2125.2006.02698.x
- Peltzer K, Pengpid K. Prevalence and determinants of traditional, complementary and alternative medicine provider use among adults from 32 countries. *Chin J Integr Med*. (2018) 24:584–90. doi: 10.1007/s11655-016-2748-y
- Kemppainen LM, Kemppainen TT, Reippainen JA, Salmenniemi ST, Vuolanto PH. Use of complementary and alternative medicine in Europe: health-related and sociodemographic determinants. *Scand J Public Health*. (2018) 46:448–55. doi: 10.1177/1403494817733869
- Seo H-J, Baek S-M, Kim SG, Kim T-H, Choi SM. Prevalence of complementary and alternative medicine use in a community-based population in South Korea: a systematic review. *Complement Ther Med*. (2013) 21:260–71. doi: 10.1016/j.ctim.2013.03.001
- Keene MR, Heslop IM, Sabesan SS, Glass BD. Complementary and alternative medicine use in cancer: a systematic review. *Complement Ther Clin Pract*. (2019) 35:33–47. doi: 10.1016/j.ctcp.2019.01.004
- Bishop FL, Rea A, Lewith H, Chan YK, Saville J, Prescott P, et al. Complementary medicine use by men with prostate cancer: a systematic review of prevalence studies. *Prostate Cancer Prostatic Dis*. (2011) 14:1–13. doi: 10.1038/pcan.2010.38
- Murthy V, Sibbritt DW, Adams J. An integrative review of complementary and alternative medicine use for back pain: a focus on prevalence, reasons for use, influential factors, self-perceived effectiveness, and communication. *Spine J*. (2015) 15:1870–83. doi: 10.1016/j.spinee.2015.04.049
- Eardley S, Bishop FL, Prescott P, Cardini F, Brinkhaus B, Santos-Rey K, et al. A systematic literature review of complementary and alternative medicine prevalence in EU. *Forsch Komplementarmed*. (2012) 19 (Suppl.2):18–28. doi: 10.1159/000342708
- Frass M, Strassl RP, Friehs H, Müllner M, Kundi M, Kaye AD. Use and acceptance of complementary and alternative medicine among the general population and medical personnel: a systematic review. *Ochsner J*. (2012) 12:45–56.

43. Yang L, Sibbritt D, Adams J. A critical review of complementary and alternative medicine use among people with arthritis: a focus upon prevalence, cost, user profiles, motivation, decision-making, perceived benefits and communication. *Rheumatol Int.* (2017) 37:337–51. doi: 10.1007/s00296-016-3616-y
44. Wang Y, Xie C, Wang W-W, Lu L, Fu D, Wang X, et al. Epidemiology of complementary and alternative medicine use in patients with Parkinson's disease. *J Clin Neurosci.* (2013) 20:1062–7. doi: 10.1016/j.jocn.2012.10.022
45. Chang H, Wallis M, Tiralongo E. Use of complementary and alternative medicine among people living with diabetes: literature review. *J Adv Nurs.* (2007) 58:307–19. doi: 10.1111/j.1365-2648.2007.04291.x
46. Solomon D, Adams J. The use of complementary and alternative medicine in adults with depressive disorders. A critical integrative review. *J Affect Disord.* (2015) 179:101–13. doi: 10.1016/j.jad.2015.03.031
47. Alsanad S, Aboushanab T, Khalil M, Alkhamees OA. A descriptive review of the prevalence and usage of traditional and complementary medicine among saudi diabetic patients. *Scientifica.* (2018) 2018:6303190. doi: 10.1155/2018/6303190
48. *Pravilnik O Načinu Oglašavanja Leka, Odnosno Medicinskog Sredstva.* “Sl. glasnik RS”, br. 79/2010 i 102/2018 (2018). Available online at: https://www.paragraf.rs/propisi/pravilnik_o_nacinu_oglasavanja_leka_odnosno_medicinskog_sredstva.html (accessed June 20, 2019).
49. Bochenek T, Godman B, Lipowska K, Mikrut K, Zuziak S, Pedzisz M, et al. Over-the-counter medicine and dietary supplement consumption among academic youth in Poland. *Expert Rev Pharmacoecon Outcomes Res.* (2016) 16:199–205. doi: 10.1586/14737167.2016.1154790
50. Jakovljevic MB, Djordjevic V, Markovic V, Milovanovic O, Rancic NK, Cupara SM. Cross-sectional survey on complementary and alternative medicine awareness among health care professionals and students using CHBQ questionnaire in a Balkan country. *Chin J Integr Med.* (2013) 19:650–5. doi: 10.1007/s11655-013-1434-6
51. Sewitch MJ, Rajput Y. A literature review of complementary and alternative medicine use by colorectal cancer patients. *Complement Ther Clin Pract.* (2010) 16:52–6. doi: 10.1016/j.ctcp.2009.10.001

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Employee Acceptance of Use: A Precondition for Enhancing Therapy Effectiveness, Patient Safety, and Economic Efficiency

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Introduction: From the workplace engineering sciences, it is evident that work efficiency, measured by the criteria efficiency and effectiveness of therapy, economy and patient safety, is determined mainly by staff acceptance of new technology and reengineered workflows. Accordingly, the aim of this study was to ascertain and assess differences in terms of the acceptance of alternative types of prosthesis instrument configurations, oriented around the research question: “Which product features and process effects determine a high level of employee acceptance of use?”

Materials and Methods: This study is designed as a before-and-after comparison, based on the usability engineering approach. In the first study phase, 46 employees participating in the process of providing instruments for a total knee arthroplasty (TKA) procedure were asked to examine the current working situation, using a standard instrumentation set, in terms of instrument handling, work burden, proneness to errors, patient risks, process efficiency, and effectiveness. In the second study phase, 20 weeks after having implemented a size-specific instrumentation set, the same 46 individuals were surveyed on the identical questions. Additionally, in both study phases the time needed to perform the sub-processes related to instrumentation logistics inside the operating room (OR) was measured, in order to identify process efficiency and cost-saving effects.

Results: By using standard sets only 30% perceived a need for improvement. After 20 weeks, only 8% of the employees were satisfied with the previous equipment and 69% regarded the standard set as being relatively error-prone, endangering patient safety. In addition, 85% regarded the effectiveness of the standard process as limited. Finally, 75% considered the effectiveness of the reengineered process to be significantly higher, and 69% drew attention to the reduction of handling disadvantages. Furthermore, the time needed for instrumentation logistics inside the OR estimated at about 13 min less when using size-specific sets. This effect on process efficiency cost savings or the generation of additional revenue by performing additional procedures. Based on these findings, an ergonomic decision-making model has been developed.

Conclusion: Innovative medical products such as size-specific instrumentation sets contribute to lower procedure costs and improved process efficiency in the operating room (OR). However, employee motivation to use a new technology as part of an optimized workflow organization, is crucial to achieving an enhanced level of effectiveness, efficiency and patient safety. Hence, it is advisable to enhance change-management efforts in order to reduce resistance to change and ensure the new technology is successful.

Keywords: change management, innovative technology, ergonomic model, patient safety, opportunity costs, theater workflow efficiency

INTRODUCTION

Innovative technologies, in combination with the optimization of clinical processes [e.g., introduction of surgical robots for radical prostatectomies; size-specific instrumentation sets in total knee arthroplasty (1–3)], is generally stated as the most effective way of gaining cost savings in hospitals (4) and simultaneously ensuring workplace effectiveness. We know from economic analysis and industrial ergonomic research (5) that there is a direct cause and effect correlation between a fatigue-proof work system design and productivity and quality. The same effects have also been demonstrated in various empirical studies in the field of behavioral work research [also refer to the “Hawthorne Effect” (6, 7)], as well as individual motivation theories [such as the “Dual Factor Theory” by Herzberg (8)].

Hospital research into the correlation between the design of the working environment and workplace equipment, on the one hand, and working effectiveness as well as patient risks, on the other hand, demonstrates that impairments due to stress factors from poor workplace equipment and related issues, have an adverse effect on the well-being of employees in clinical areas and lead to mistakes at work. This is the research focus of the “Healing Environment Approach” (9, 10). Empirical findings into the correlation between well-being in the workplace, on the one hand, and working efficiency and possible errors, on the other hand, are of particular importance. Distractions, which disturb ones’ concentration exert a negative impact on working effectiveness and on the risk of employee errors. In this regard, various studies have examined a direct cause and effect correlation between the comfort of wearing OR (operating room) clothing and working efficiency, or the potential for errors to be made by OR personnel. For example the “Karmasin Study” (11) is based on the working hypothesis, that the comfort of surgical gowns (expressed by the quantifiable criterion “body temperature”), can influence the performance of surgeons to the extent that poor breathing of textile materials can trigger heat stress during longer surgical procedures (lasting more than 2 h), which can have an adverse impact on psychomotor characteristics (12).

A second aspect of acceptance research refers to the fact that innovative technologies are associated with changes in workflow organization and disruptions in interworking patterns. Many employees fear fulfilling the requirements of the new work environment and assume

there is a risk of being burdened by additional tasks and responsibilities.

Acceptance of a new technology and the associated reorganization measures is more likely, particularly if the people affected by and those involved in a reorganization can be persuaded that:

- A problem exists objectively within the working process which has a considerable impact upon the situation of every individual in the workplace,
- The current situation is associated with risks to the process (for example, patient outcome), or
- The overall working situation can be improved for everyone concerned by introducing a new organizational / technical concept, including with a view toward lowering costs.

Examples of the types of “improvements” which are typically requested by employees and which encourage acceptance are (13–16):

- Less work and reduced time pressure,
- Better orientation within the working process,
- Self-determination in clinical decision-making and independence from third-party work results,
- Reliability within the working process, thus making the process more fail-safe as far as the patient is concerned.

Despite these employee requirements with respect to bringing medical products with handling advantages into the working process, many hospitals prefer a price-driven procurement policy due to increasing financial pressure. Accordingly, for purchasing officers in hospitals, the price of a product is the dominant criterion when selecting and buying a medical product. Handling advantages, procedure time reduction and patient safety aspects play only a minor role in the purchasing criteria catalog. This restrictive purchasing philosophy in many hospitals is a major hurdle to bringing innovative products into practice (17).

GOAL

The overall aim of the study was to determine the importance of employee acceptance-to-work on process efficiency in the OR, tested by a planned organizational change of instrumentation sets. It was thus intended to ascertain and assess differences

in terms of the acceptance of alternative types of prosthesis-instrument configurations (standard vs. size-specific instrument trays) used in total knee arthroplasty (TKA). The guiding research question was: “Which product features and process effects caused by the instrument configuration determine a high level of acceptance of use?” Furthermore, the following research hypothesis was tested and confirmed: “Employee acceptance of standard instrumentation sets is significantly lower than that of size-specific sets.”

Major objectives were to determine whether innovative medical products contribute to reducing procedure time in the OR, as well as leading to cost savings, and to determine whether handling complexity caused by medical products influences the acceptance-to-work of employees.

The study was conducted in two phases, whereby specific objectives were set for each phase.

The aim of the first study phase was to examine how satisfied employees are with the existing technical equipment, based on standard instrument sets used in a total knee arthroplasty procedure. The purpose of this first acceptance study was to establish whether and to what extent employees feel that there is a need to change the instrumentation-management process. The subsequent analysis of the organizational workflow of the instrument logistics aimed to:

- Identify existing medical, economic, organizational workflow or risk-related weaknesses and thus to
- Confirm the need to make changes to the organizational workflow.
- Furthermore, constructive change-management measures should be derived from these findings which help to:
- Accelerate learning curve effects (18, 19).
- Afterwards, the findings of this acceptance survey in the first study phase were ultimately factored into the specifications for the decision on the selection of new instrumentation equipment, based on size-specific surgical trays.

The aim of the second study phase was to identify differences in the acceptance behavior of employees involved in the process of instrumentation management as surgeon, scrub nurse or technician in the central sterilization department (CSSD).

MATERIALS AND METHODS

This investigation is designed as a “structural study,” a type oriented to the “Social System Approach” by Luhmann (20) and typically used in Human Relations Research represented for example by Sanders and Kianty (21). A structural study aims to identify the patterns, dynamics and stability of an organizational system (22–24) which is described by the design elements “task,” “person,” “device,” “information,” “space,” “time,” “relations” (25) and “institutions” (26). The term “institutions” refers to official rules, regulations, agreements and unwritten rules (27). Institutions are the driving factors of a socio-technical system. The productivity of a socio-technical system such as a hospital is measured by the variance in the output of this system (28).

Especially in the field of Industrial Ergonomics the “Usability Engineering Approach” of Backhaus (29), as well as the “Analytic Job Evaluation” via workload-stress-concept of Rohmert (30) are used for observational workplace research with the number of participants limited between 5 and 20. Furthermore, in lean management theory, especially in the area of patient safety through product design, standardization and work-cell design (31, 32), the generic structure of a process helps identify cause-and-effect relations as well as typical pitfalls in the process. The essence of the study is a “usability test” of an innovative size-specific instrumentation set configuration (size-specific set). Usability tests as carried out in the present study are observational studies of work systems and workflows and are quite different to the study types normally used in clinical or epidemiological studies (cohort, case control, prevalence studies). These study types are common for testing innovative procedures (e.g., TAVI: Transapical Aortic Valve Implantation) or new drugs (e.g., Multiple Sclerosis treatment regime based on Rituximab) and require more participants ($n > 500$) for ensuring statistical validity and reliability. For usability tests a minimum cohort of 5–20 procedures is recommended (33–35).

This study was conducted in a university hospital, commencing in March 2017 with the study design and the documentation of results and findings was completed in September 2018. All data related to this study excluded patient-specific data. The staff council, as the legal representative of employees in Germany (participants), consented to support the study. According to both German and European regulations, performing and publishing this study does not require ethical approval (36). Furthermore, surgical departments in Europe are free to decide which surgical instruments they use for performing a procedure, provided these instruments have been approved by a notified body (37). In this study, only instruments such approved and certified with a CE mark (Conformité Européenne) and/or conformity assessment were employed. Finally, the medical products utilized all fulfill the requirements of German (38) and European Union Law (39).

The current acceptance analysis entails a before-and-after comparison between standard sets and size-specific instrument sets. Several implants and types of sets are available on the market. In our study as well as in our practice, we use a “tibia-first” system for performing a Total Knee Arthroplasty (TKA) procedure. We start by preparing the tibial plateau and adjust further operative technical steps accordingly. Further, we performed non-navigated TKA. In all cases, the patella was not everted, the posterior cruciate ligament was retained and the collateral ligaments remained intact.

Size-specific trays only contain size-related instruments e.g., cutting guides and trial implants. These instruments are only suitable for a defined implant size, so that the surgeon has to anticipate the size of the relevant components prior to starting the procedure, based on preoperative planning. The final decision is made intraoperatively, according to the local findings and intraoperative measurement. The size of a tibial component can be measured by referring to the size of the tibial plateau after superficial bony resection. The femoral component is measured prior to bony resection. The size of the inlay always corresponds

to the size of the femoral component. The thickness (height) of the inlay is measured by referring to the extension- and flexion-gap and must ensure stability as well as a sufficient range of motion. From the logistical point of view, the availability on call of different sterile trays containing possible sizes must be ensured in order to prevent any outcome risks to the patient.

In the survey, the employees involved in the sub-processes of “instrument preparation” and “cleaning up the OR,” as well as the staff responsible for cleaning and reprocessing the sets and the surgeons performing the TKA procedure, were asked via questionnaire and interviewed on the following criteria:

- Overall satisfaction with the respective instrumentation set in order to recognize any general need for change and to render areas of improvement transparent.
- Process effectivity, defined as the contribution of an instrumentation set to shorter turn-around-times, reduced risks and lower costs.
- Workload and time pressure in the workflow.
- Effectivity of quality control.
- Handling.
- Susceptibility to error.

After having delivered the completed questionnaire, all employees participating in the study were interviewed one-on-one about the reasons underlying their evaluation of the current instrumentation setting.

The survey was conducted among 46 employees (8 surgeons, 20 scrub nurses, 18 CSSD technicians) in two study phases. The first study phase (starting situation with standard set configuration) aimed at determining to what extent from the viewpoint of employees, a change in the instrumentation organization is necessary. In the second study phase carried out 20 weeks after having implemented the size-specific set type, a second acceptance analysis was accomplished in order to determine changes in employee acceptance, especially referring to “process effectiveness” and “susceptibility to error.”

In order to identify differences in process efficiency between the various instrument settings the time needed for performing the two sub-processes “preparation of all instruments” and “clearing up of used and unused instruments” was measured. “Duration” of a sub-process related to instrumentation logistics can validly be used as a proxy for process efficiency and cost savings. A reduced OR occupation time possibly allows performing an additional procedure, which yields additional revenue and contributes to avoiding higher paid overtime for the OR staff in the afternoon of a working day in the theater. Accordingly, 14 TKA procedures with standard sets and 18 TKA performed with a size-specific set were observed and the durations of the sub-processes relevant for instrumentation management were measured. Only procedures were observed in which the 46 selected employees were involved. By using this approach, confounding effects due to different learning curves and skill bases of employees, could largely be eliminated. All comparison figures and measures used are composed on **Table 1**.

RESULTS

The results are segmented into five areas of appraisal criteria.

(1) Employee satisfaction with current situation

Nearly every third employee (31%) was dissatisfied with the original situation (standard instrument system) and expressed a need for change (see **Figure 1**). The initially high proportion (~70%) of employees who were satisfied (more precisely: “not dissatisfied”) is attributable, among other things, to two phenomena:

- A lack of understanding of a better alternative;
- Reluctance due to fears relative to an uncertain reorganization.

This is illustrated by the assessment of process effectiveness (see **Figure 2**), which is interpreted as the “contribution made by the organization of the process (including the use of technology) to shorter instrument cycle times, reduced risk of errors and lower costs.”

According to that, only about 8% of the employees were really satisfied with the standard system. They were particularly critical of:

- The high weight of the trays,
- The time-consuming preparation process, as well as
- Avoidable stress resulting from a high number of surgical interventions with a limited time allowance, exacerbated by the instrument-management process.

Furthermore, the employees addressed the fact that there is a direct cause and effect relationship between the “quantity of instruments,” on the one hand, and “time pressure during the process workflow” and the “effectiveness of quality control,” on the other hand.

(2) Process effectiveness

This is defined here as the contribution of the process organization to shorter turn-around-times, reduced workflow risks for staff and patient, and top lower costs.

The employees rated the effectiveness of the standard system as “effective to a limited extent” (69.2%) or “minimally effective” (15.4%). This assessment is shared by scrub nurses and CSSD personnel alike, as well as by surgeons, albeit for other reasons. The surgeons are critical of the lack of clarity as to what is in the trays, the CSSD personnel bemoan the weight of the trays, time pressure and complexity of the process, and the scrub nurses complain about a shortage of space to accommodate the trays in the OR.

(3) Proneness to error

The proneness of the standard system to errors, due to its complexity, is also regarded as significantly high at almost 70% (see **Figure 3**).

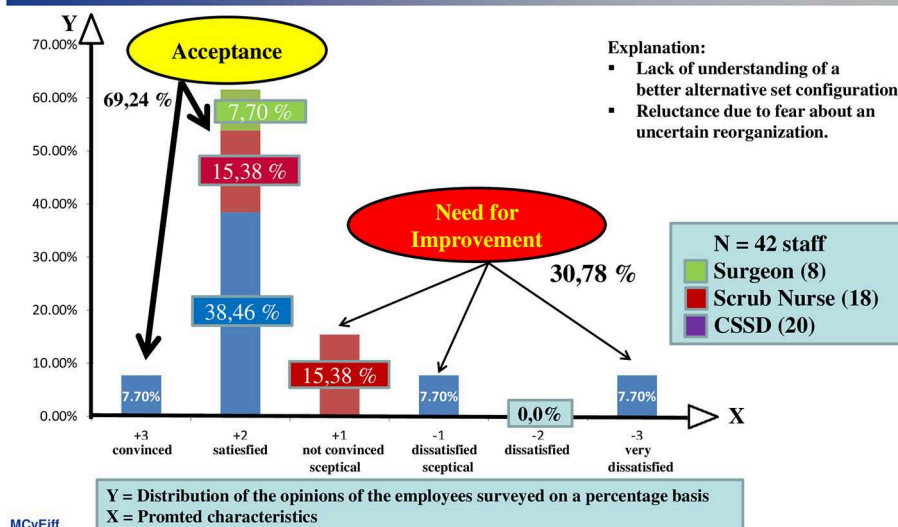
(4) Complexity of handling and clarity of arrangement of instruments on trays

TABLE 1 | Figures, definitions, and measures used to run the comparison between two medical products and the two types of process these products characterize.**Definitions of key figures and measures****Efficiency and effectiveness of a product (here: prosthesis and instrumentation system) are measured by selected and well-defined figures**

Key figure	Definition	Measure
Degree of satisfaction with a product or workflow	Product dysfunctionalities as well as working areas and workflow elements employees identify to be improved.	Questionnaire Likert scale
Perceived process effectiveness	Contribution of the process organization to shorter turn-around times, reduced risks and lower costs.	Questionnaire Likert scale
Perceived proneness to error	Probability employees perceive due to dysfunctional organization and handling disadvantages of products used.	Questionnaire Likert scale
Complexity	Number and variety of elements and interactions determining the character of a socio-technical system.	Number of instruments prepared for a procedure organized on a tray Proportion of instruments used Number of trays Floor space needed for instrumentation logistics (No. of instrumentation tables; square meters of space occupied inside OR)
Economic process effectiveness (measured via process and work analysis)	Contribution of the process organization to shorter turn-around times and lower costs.	Duration of a (sub-) process Resources needed to operate a process (working hours; salary; OR capacity)
Economic process efficiency (measured via process and work analysis)	Contribution of a process to reduced need of resources	Preparation time of instruments Cleaning up time Total process time Working time used as a proxy to determine costs and opportunity costs Overtime payment OR blockade time

Degree of satisfaction

Some 30 % of employees were not satisfied with the original situation (project phase 1, standard instrumentation system) and indicated possible areas of improvement.

**FIGURE 1** | Despite a high general acceptance of the existing system, almost one third of employees felt that there was a need for improvement.

All of the occupational groups involved feel that the overall working system would benefit greatly if there were a significant reduction in the number of trays and

of instruments (see **Figure 4**). These advantages relate primarily to more convenient handling, greater clarity, less time pressure and a lighter workload, less error-proneness

Perceived process effectiveness

The process effectiveness of a standard instrumentation system by some 85% of the employees is rated as „limited“.

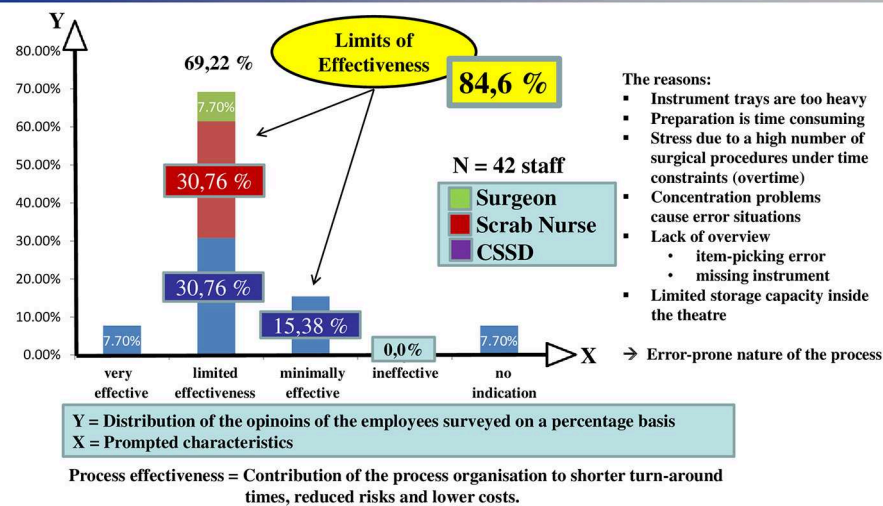


FIGURE 2 | Eighty-five percentage of employees feel that the effectiveness of the process is limited.

Susceptibility to Process Error

Some 69% of the employees questioned regard the standard system as being relatively prone to error.

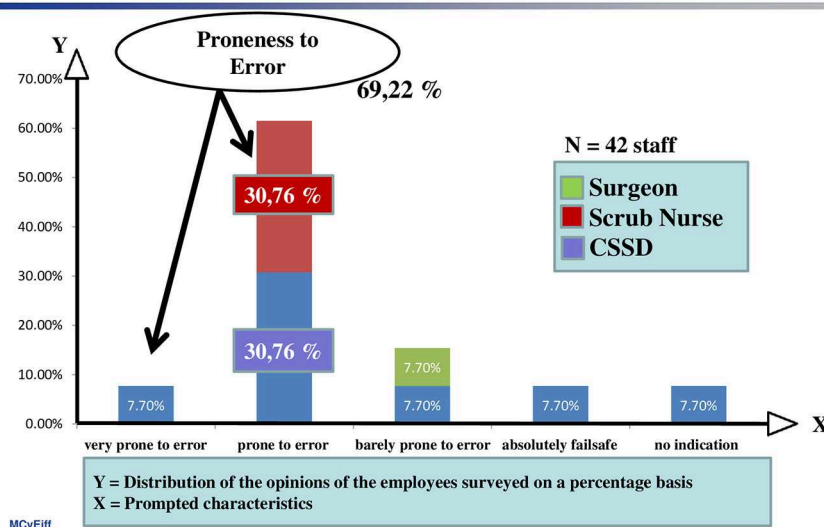


FIGURE 3 | Phenomenon of being error-prone.

as a result of simple instructions, as well as more effective quality control.

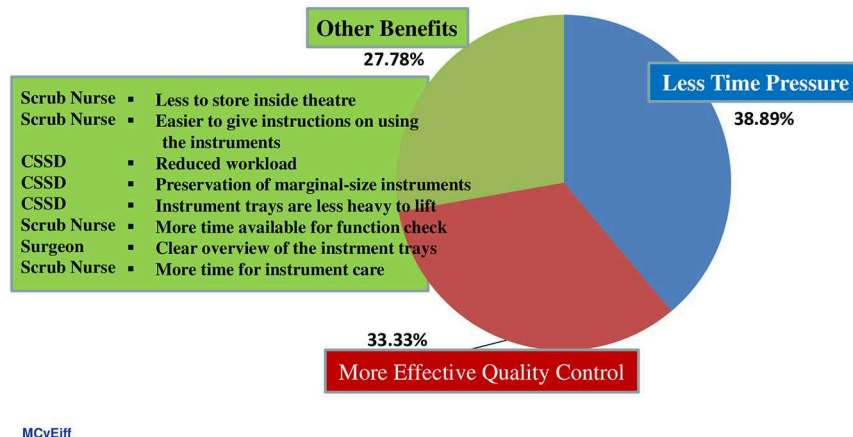
At this point, an important cause-and-effect relation emerges: complexity and handling comfortability are experienced in terms of the weight and number of trays, which have to be used in

the theater. Furthermore, the number of instruments arranged on a tray is a complexity indicator. Another complexity measure is the percentage of instruments transported back to the CSSD for reprocessing, without having been used during the TKA procedure. The before-after comparison demonstrates the use of

Quantity of instruments

The quantity of instruments has a bearing on „time pressure“, „quality control“, and the „general working environment“.

„A significantly lower number of instruments means ...“



MCvEiff

FIGURE 4 | Clear organizational advantages will be achieved by reducing the number of trays and instruments.

TABLE 2 | The proportion of instruments placed on a tray, but not used during the procedure is a proxy indicator for work complexity and cost.

The complexity of a prosthesis and instrumentation system is an important cost driver as well as a hidden source of failures within the scope of the instrument cycle

Criteria	Standard setting	Size-specific setting	Reduction in complexity (%)
Sample size	14	18	–
Number of instruments prepared	156	91	42.67%
Proportion of instruments used	32.67%	54.64%	40.21%
Number of trays	6	3	50%

standard instrumentation systems seems to be accompanied by a higher degree of complexity (see **Table 2**).

As a result of the first study phase, it is evident that the personnel is generally in favor of a reduction in the number of trays and instruments.

Some 20 weeks after the introduction of the size-specific system, a second acceptance study was conducted in order to gauge how satisfied the personnel were with the new instrument logistics solution. The before-and-after comparison reveals a marked rise in perceived process effectiveness, i.e., in the contribution of the process organization toward shorter turnaround times, reduced risks and lower costs (see **Figure 5**).

Obviously, there is a very tight cause-and-effect relationship between the acceptance of an instrumentation setting and the quantity of instruments and number of trays used. Acceptance of a care variant with OR trays is essentially determined by the number of trays and the number of instruments placed in the trays. The number of instruments, which are not used, but are reprocessed, has a particularly negative effect.

There was also a clear improvement in satisfaction in terms of being “error-prone” (see **Figure 6**). For instance, 69% of those questioned regarded the standard system in the original situation as error-prone, whereas the size-specific organization was only classed as error-prone by 25%.

(5) Process efficiency

In this context process efficiency is defined as the relation between an input of resources e.g., personnel, medical products as well as devices, and the result gained by combining these resources in a well-organized medical procedure. Process efficiency is measured by the duration of uniquely defined sub-processes, the number of instruments used in relation to the number of instruments placed on a tray when starting the procedure and the direct costs as well as the opportunity costs caused by a procedure.

Opportunity costs are understood as a benefit, gain or value of something that must be given up to acquire or achieve something

Perceived process effectiveness: a before and after comparison

The process effectiveness of a size-specific instrumentation set is rated as „highly effective“ by the OR and CSSD staff. Endpoints of measurement: preparation and cleaning-up time in the OR and TAT inside CSSD.

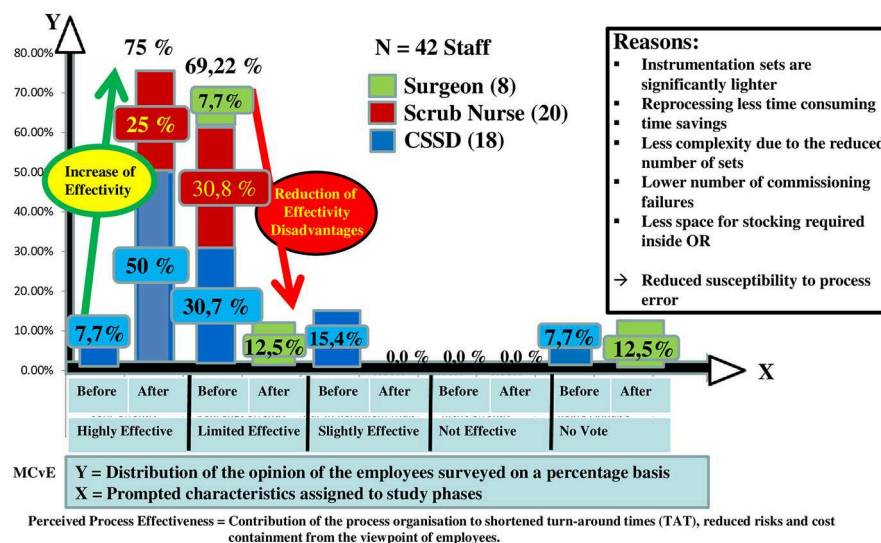


FIGURE 5 | The before-and-after comparison shows a marked rise in perceived effectiveness.

Perceived proneness to error of the process in the before-and-after comparison

The employees questioned confirm that the size-specific instrumentation system is much less prone to error than the standard system used in the starting situation.

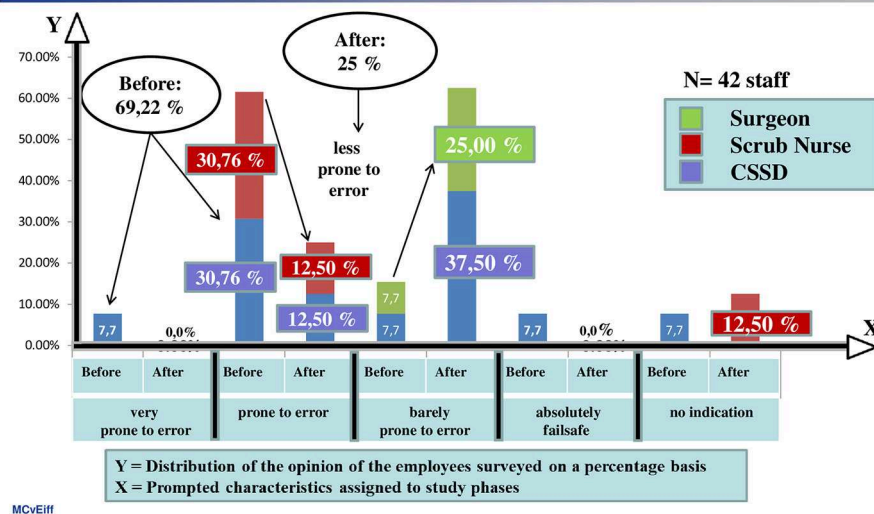


FIGURE 6 | A size-specific, standardized instrument system reduces the degree to which the instrument management is error-prone.

else (40, 41). Typical opportunity costs appear when for example an OR is blocked due to an extended procedure time as a consequence of non-availability of medical products needed for the procedure, or when a bed is occupied because a patient acquired a nosocomial infection.

In addition to these findings, using size-specific instrument sets contributes significantly to shortening the duration of the sub-processes for “preparing instrumentation equipment before starting operation” (incision time) and “cleaning up of used and unused instruments” after the surgeon has finished the procedure

(suture time). “Process time” can be used as a proxy for process efficiency, because the time saved can be used alternatively for performing an additional procedure that yields additional revenue or for avoiding expensive overtime hours for the staff in the afternoon of a working day in the OR. In order to obtain evidence on this issue, a generic process model was constructed, which depicted the sub-processes performed in the context of a TKA procedure (see Figure 7).

The total process for the instrument handling was reduced from 28:45 to 15:08 min, which corresponds to a time gain and reduction of the occupancy time

of the OR of 13:22 min (53%) for one TKA operated (see Table 3).

On premise that 4 TKA are performed over one working period per day, the theater is occupied for 08:35:00 h. A time reduction of 13:22 min per TKA procedure leads to a reduced occupancy time of the OR by 53:28 min on average. This time saved can be used to perform an additional procedure, e.g., an Arthroscopy (including biopsy). The procedure time is usually 30 min, so that two efficiency effects can be identified:

- The total theater occupation time is reduced from 08:35 to 08:30 h.

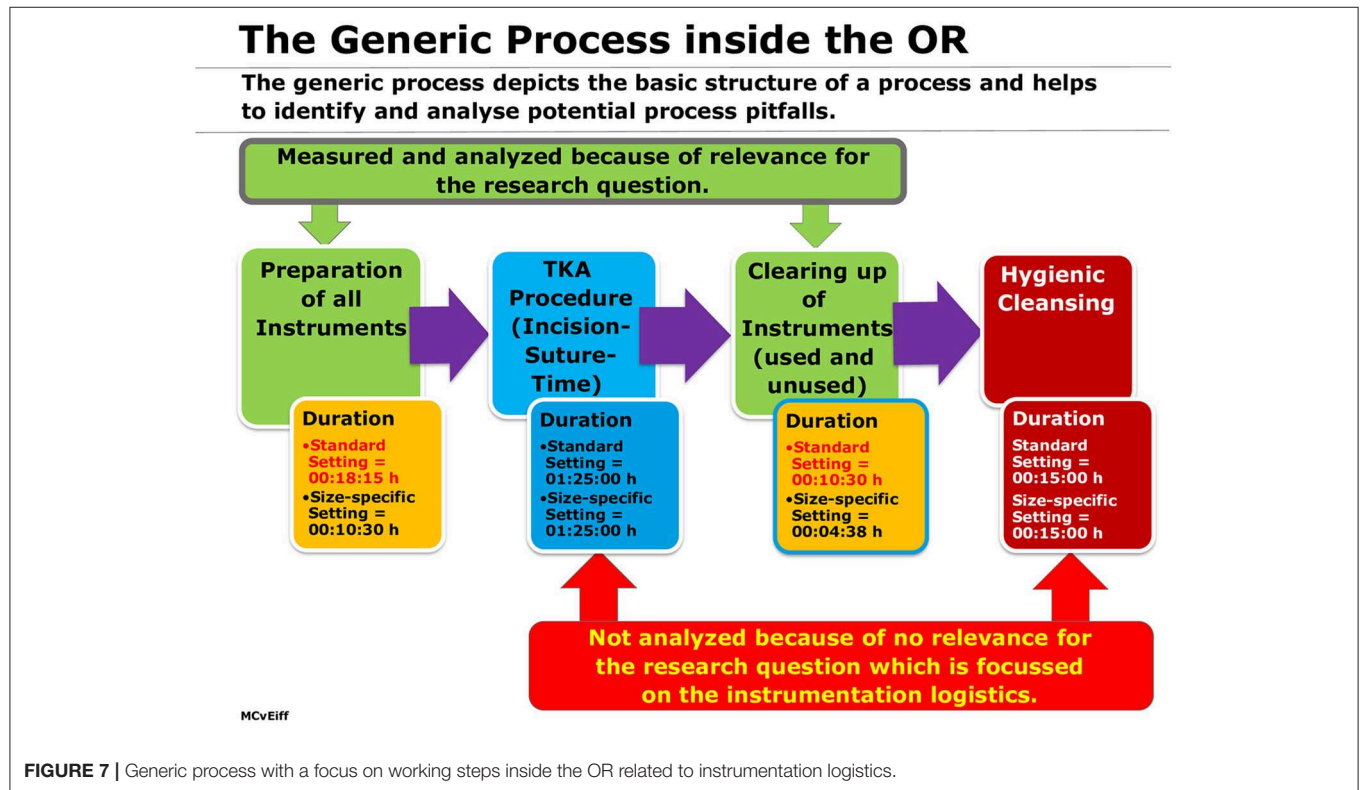


TABLE 3 | Comparison of the durations of sub-processes related to instrumentation logistics.

Process efficiency

The duration of the sub-processes related to instrumentation logistics is significantly (53%) shorter when using size-specific instrument sets, a remarkable contribution to process efficiency and cost reduction.

Sub-process in the OR	Standard instrument-tation set (duration: min.)	Size-specific s instrument-tation set (duration: min.)	Time saved (min.)
Preparation of all Instruments	18:15	10:45	07:30
Cleaning up OR	10:30	04:38	05:52
Total process time	28:45	15:23	13:22

Opportunity cost calculation:

If 4 Total Knee Arthroplasty procedures (TKA) were performed in one

OR a day 53 min will be saved

This time gained can be used for

Avoiding overtime in the afternoon or

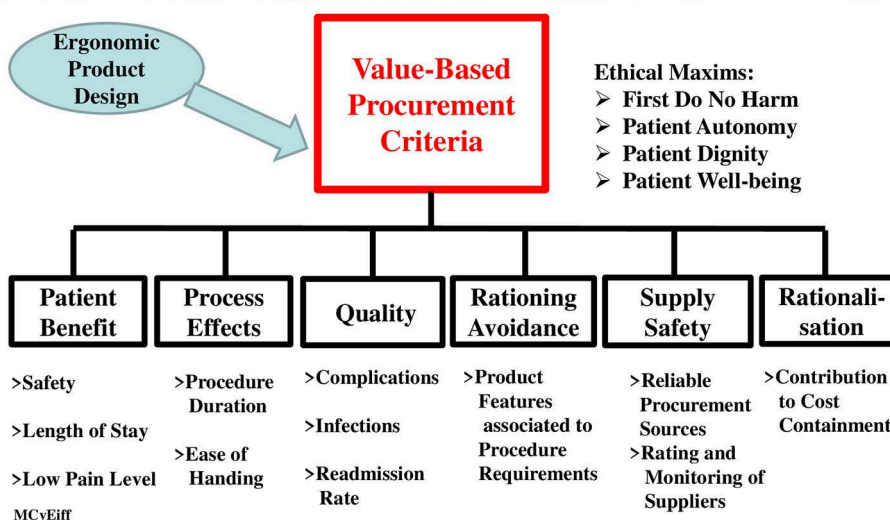
Performing an another procedure achieving additional revenue

TABLE 4 | Results according to selected criteria.

Table of results			
Criteria	Standard set	Size-specific set	Remarks
Work Complexity			
No. of sets	6 sets	3 sets	Number of sets and instruments determine workplace complexity and influence handling and safety of the procedure
No. of Instruments prepared	156	91	
Floor space needed for instrumentation logistics	high	low	
Efficiency			
OR occupation time	28:45 min	15:23 min	Time saved is a proxy for process efficiency and cost reduction
(instrumentation-related) Instruments used (proportion)	32.67%	54.64%	
Process effectiveness = contribution to shortened turn-around-times, reduced risks and cost containment	Employees judge “limited” (69%) or “minimal effective” (15%) 7.7% judge “highly effective”	12.5% judge “limited effective” 75% judge “highly effective”	Individual opinion of employees (nominal measurement by Likert scale)
Handling advantages	High weight of sets	Less heavy to lift the sets	Individual opinion of employees (Likert scale)
Safety			
Overview (instrument trays) Instructions/Learning Curve	Limited overview Complicated to give Instructions to scrub Nurses and assistants	Clear overview Ease of giving instructions how to handle instruments	Individual opinion of employees (Likert scale)
Proneness to error quota	69% quota	25% quota	
Opportunity costs and opportunity benefits	Opportunity costs = 1.671€	Opportunity benefits = 53:28 min. time saving p. theater day	Time savings usable for overtime reduction or an additional procedure
Overall aspects	Cumbersome set handling leads to time consuming working steps and press of work	Less time pressure More effective quality Control More convenient handling	Size-specific sets contribute to a significant higher level of employee job satisfaction

Decision-Making Criteria

Value-based procurement management is committed to comply with ethical requirements and economic rationale while performing patient experience.

**FIGURE 8 |** Decision-making criteria in a value-based procurement approach.

- For the additional procedure (Arthroscopy) in the German DRG reimbursement system the statutory medical funds pay € 2.564 (G-DRG I24A; cost weight: 0,723; base rate: € 3.535) (42). For measuring the financial return from a surgical procedure the “Direct Costing Method” is generally used (43). In the case described, the contribution margin I (CM I = DRG reward minus variable costs of the procedure) is used to define the opportunity costs of a non-performed procedure (in this case = € 1.671) and the contribution margin II (CM II = CM I minus fixed costs associated with the procedure) defines the profit of the department before reduced by the allocatable costs of the hospital (44).

(6) Summary of results

The table of results (see **Table 4**) summarizes the major findings of the study and indicates the superiority of size-specific instrument trays. Moreover, it is evident that the sustainable success of innovative medical technologies in practice e.g., new products, re-organized workflows or disruptive procedures, depends on the acceptance-to-work of the employees working in the re-organized process. And this acceptance is heavily influenced by the impact of the innovative technology on procedure handling, costs, workflow efficiency, and patient safety. All these aspects are a direct result of the nature of design of an innovative technology.

DISCUSSION

This comparative analysis demonstrates a significant improvement in process effectiveness in terms of shortened

turn-around times, reduced risks and lower costs. Also, the susceptibility to error caused by the complexity of the standard instrumentation set was originally rated significantly higher (70%).

This study also demonstrates that a lower number of instruments arranged on a tray contributes to a more stress-free and ergonomic work environment, to more effective quality control and a reduction in time pressure.

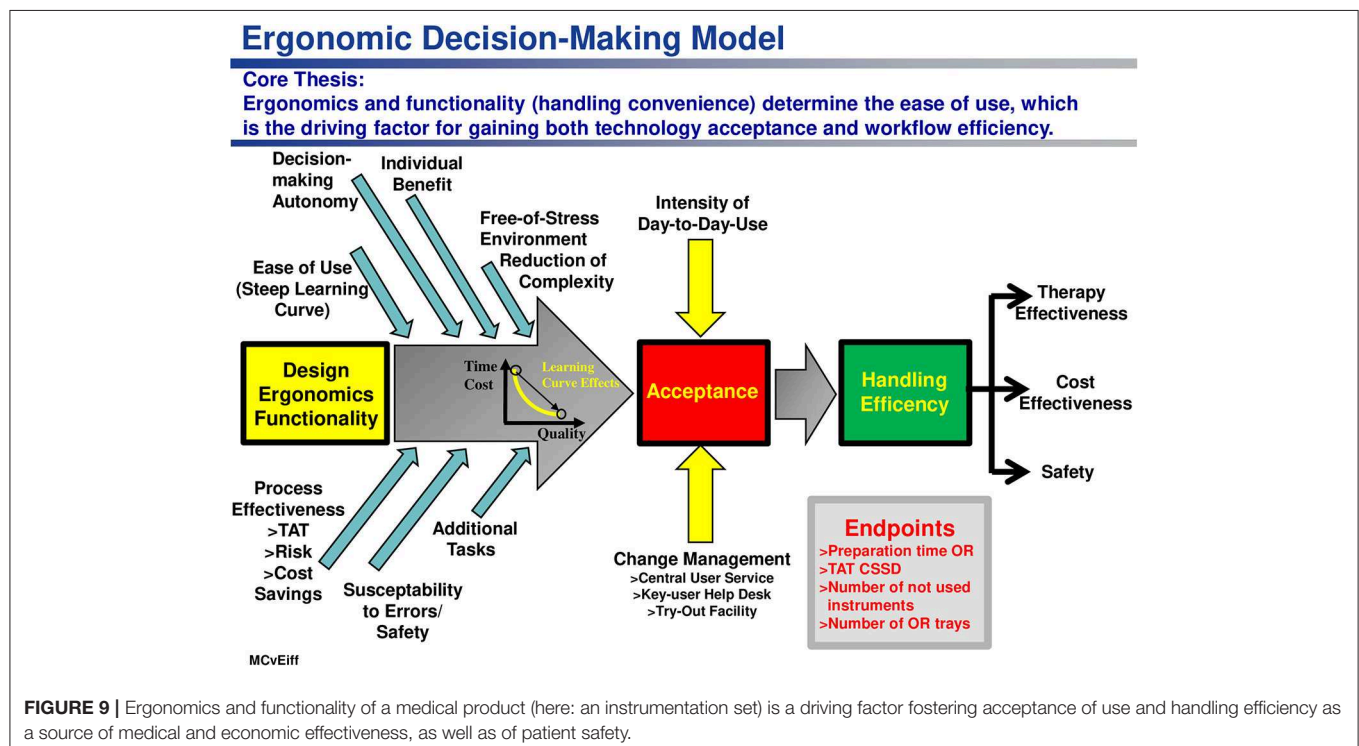
Another important finding concerns the change management organization, which is crucial for the economic success of a new implemented technology or workflow.

Moreover, it should be noted that the quality of change-management (key user support, help desk, training, tryout opportunities) contributes to shortening the learning phase and raising acceptance.

Furthermore, it is evident that the percentage of employees who class an instrument system as “error-prone” after a switchover is all the higher, the shorter the period of time between the system switchover and the acceptance study. The reason for this is that a short timeframe does not permit learning-curve effects so that personnel remain rather unsure about how to use the new and unfamiliar system.

Referring to the previously mentioned price-driven procurement philosophy, which guides many hospitals, and bearing all findings of this study in mind, it is highly advisable to change the procurement policy for purchasing medical products and devices used during surgical procedures from a price-driven management approach to a value-based philosophy.

The value of a medical procedure is defined as the relation between patient outcome, patient safety, procedure time, patient



pain level and patient length of stay on the one hand, and procedure costs on the other hand. Accordingly, the most important assessment criteria (45) for selecting the right medical product within the frame of a procurement decision-making process are “usability” (ease of use, avoidance of patient risks, low workload), learning-curve effects and reduced process time (see **Figure 8**).

From all these preliminary considerations, an ergonomic decision-making model (46) can be derived (see **Figure 9**) which establishes a relationship between

- The functionality of the OR trays used,
- The intervention-specific framework conditions within the OR,
- The satisfaction with the tray configuration by OR personnel on the one hand, and the
- Working efficiency as well as the
- Outcome variables of an OR process (process effectiveness, theater blocking time, cost effectiveness, degree of dissatisfaction on the part of the OR personnel, patient safety), on the other hand.

CONCLUSION

The design, ergonomics and functionality of innovative medical products have a tremendous impact via the ease of handling, on costs, therapy effective-ness, work environmental and patient safety.

Given that ease of handling directly influences employee acceptance of a re-engineered process or an innovative medical product or disruptive technology, this can be regarded as a crucial precondition for the efficiency and effectiveness of workflows.

LIMITATIONS OF THIS STUDY

One limitation of the analysis is that clear recommendations pertaining successful change- management strategies and effective change management tools cannot be derived so far

in this context. Further research and practical tests of selected organization-development interventions are needed.

A second limitation is that learning-curve effects could not identified and measured, due to a lack of robust criteria. Thus, the “time saved” in the sub-process of instrumentation logistics was used as a proxy for deriving information about process efficiency.

Thirdly, the analysis of opportunity costs is based on the premise that the department is working at full capacity. Yet, due to a lack of qualified staff in the German health care system, the number of hospitals working at only 70–75% capacity utilization is rising.

Furthermore, additional research aiming to identify differences in patient outcome in changing technology settings, should be intensified.

DATA AVAILABILITY STATEMENT

The datasets generated are not available for third parties due to data security requirements of staff-related data. Requests to access the datasets should be directed to WE, von.eiff@uni-muenster.de.

AUTHOR CONTRIBUTIONS

ME, WE, and MG developed the study design. ME designed the questionnaires, prepared the data analysis, wrote the first draft of the manuscript, integrated proposed revisions, and performed the manuscript revision. AR, WE, and MG wrote sections of the manuscript. AR and MG supported the data collection and obtained the permission of the work counsel. All authors read and approved the submitted version.

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REFERENCES

1. Healy WL, Rana AJ, Iorio R. Hospital economics of primary total knee arthroplasty at a teaching hospital. *Clin Orthop Relat Res.* (2011) 469:87–94. doi: 10.1007/s11999-010-1486-2
2. Hsu AR, Gross CE, Bhatia S, Levine BR. Template-directed instrumentation in total knee arthroplasty: cost savings analysis. *Orthopedics.* (2012) 35:e1596–600. doi: 10.3928/01477447-2012-1023-15
3. Tibesku CO, Hofer P, Portegies W, Ruys CJM, Fennema P. Benefits of using customized instrumentation in total knee arthroplasty: results from an activity-based costing model. *Arch Orthop Trauma Surg.* (2013) 133:405–11. doi: 10.1007/s00402-012-1667-4
4. Schmid R, Schmidt AJ. *Moderne Beschaffungsmanagement im Gesundheitswesen – Qualität.* Heidelberg: Patientensicherheit und Wirtschaftlichkeit (2018).
5. Bullinger H-J, Warnecke HJ. *Neue Organisationsformen im Unternehmen.* Berlin; Heidelberg; New York, NY: Ein Handbuch für das moderne Management (1996).
6. Roethlisberger FJ, Dickson WJ. *Counseling in an Organization.* Cambridge, MA: Harvard Business (1966).
7. Geller ES, Johnson, D. *The Anatomy of Medical Error. Preventing Harm with People-Based Patient Safety.* Virginia Beach, VA: Coastal Training Technologies Corporation(2007). p. 64–6.
8. Herzberg, F. *Work and the Nature of Man.* Cleveland, OH: Ty Crowell Co.(1966).
9. Marberry SO (editor). *Improving Healthcare with Better Building Design.* Chicago, IL: Health Administration Press (2006).
10. von Eiff MC. Healing Environment in der Notaufnahme. Effekte einer heilungsfördernden Umgebung im Krankenhaus. In: von Eiff W, Dodt C, Brachmann M, Niehues C, Fleischmann T, editors. *Management der Notaufnahme. Patientenorientierung und optimale Ressourcennutzung als strategischer Erfolgsfaktor.* Überarbeitete und

- erweiterte Auflage. 2nd ed. Stuttgart: Kohlhammer Verlag (2016). p. 478–88.
11. Karmasin-Studie. *Verwendung von Einweg-Produkten im Operationssaal. Eine quantitative Untersuchung durchgeführt von Karmasin Motivforschung*. Wien: Initiative Sicherheit im OP (2011).
 12. Cherif C, Günther E, Jatzwauk L, Mecheels S, editors. *Evaluierung von OP-Textilien. Forschungsergebnisse des BMBF-Verbundvorhabens (FZK 0330443A bis 0330446A)*. Dresden: Technische Universität (2009).
 13. Ghanem M, Schnoor J, Heyde C-E, Kuwatsch S, Bohn M, Josten C. Management strategies in hospitals. Scenario planning. *GMS Interdiscip Plastic Reconstr Surg DGPW*. (2015) 4:1–7. doi: 10.3205/iprs000065
 14. Matern U, Koneczny S, Scherrer M, Gerlings T. Arbeitsbedingungen und Sicherheit am Arbeitsplatz im OP (Working conditions and safety in the operating room). *Dtsch Arztebl*. (2006) 103:A3187–92.
 15. Hölscher U, Laurig W, Müller-Arnecke HW. *Prinziplosungen zur ergonomischen Gestaltung von Medizingeräten*. 2nd ed. Dortmund; Berlin; Dresden: Verlag Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (2008).
 16. *Unfallkassen und Berufsgenossenschaften*. p. 1–2. Available online at: www.sicheres-krankenhaus.de/operationssaal/ergonomie (accessed September 23, 2019).
 17. von Eiff W. *Monitoring des Beschaffungsmanagements im Krankenhaus. Studien zum Entscheidungsverhalten in Einkaufs- und Logistikprozessen: Wertorientierte Beschaffung als Ziel*. Bad Wörlshofen: Verlag Holzmann Medien (2018). p. 78–92.
 18. Patel VR, Thaly R, Shah K. Robotic radical prostatectomy: outcomes of 500 cases. *BJU Int*. (2007) 99:1109–1112. doi: 10.1111/j.1464-410X.2007.06762.x
 19. Witt JH, Schütte A, Wagner C, Romagnolo A, Davoudi Y, Noormohammadi H. Roboterassistierte radikale prostatektomie: hohe onkologische sicherheit und gute funktionale ergebnisse. *J Urol Urogynäkol*. (2009) 16:15–18.
 20. Luhmann N. *Soziale Systeme. Grundriss einer allgemeinen Theorie*. Frankfurt: Suhrkamp Verlag (1987).
 21. Sanders K, Kianty A. *Organisationstheorien. Eine Einführung*. Wiesbaden: Springer (2006). p. 59–75.
 22. Forrester J. *Urban Dynamics*. Third printing. Cambridge, MA: MIT (1970).
 23. Gomez P, Probst GJB. A methodological advancement of the systems approach was performed by the St. Gallen School of Management (Switzerland). Vernetztes Denken im Management. Eine Methodik des ganzheitlichen Problemlösens. In: *Die Orientierung*, Nr. 89. Bern: Schweizerische Volksbank (1987).
 24. Senge P. *The Fifth Discipline. The Art and Practice of the Learning Organisation*. New York, NY: Doubleday/Currency (1990).
 25. Bea FX, Göbel E. *Organisation. Theorie und Gestaltung*. Stuttgart: Lucius und Lucius (1999). p. 221–33 and 246–9.
 26. Coase RH. The new institutional economics. *Am Econ Rev*. (1998) 88:72–4.
 27. Scott-Morgan P. *Unwritten Rules of the Game*. New York, NY; Chicago, IL: McGraw-Hill (1994).
 28. Arthur J. *Lean Six Sigma for Hospitals. Improving Patient Safety, Patient Flow and the Bottom Line*. 2nd ed. New York, NY; Chicago, IL; San Francisco, CA: McGraw-Hill (2016).
 29. Backhaus C. *Usability Engineering in der Medizintechnik – Grundlagen, Methoden, Beispiele*. Berlin: Springer (2009).
 30. Rohmert W. Das Belastungs-Beanspruchungs-Konzept. *Z Arbeitswiss* 38:193–200 (1984).
 31. Walker D. *The Better Hospital. Excellence through Leadership and Innovation*. Berlin: Medizinisch Wissenschaftliche Verlagsgesellschaft (2015).
 32. Pande PS, Neuman RP, Cavanagh RR. *The Six Sigma Way. How GE, Motorola, and Other Top Companies Are Honing Their Performance*. New York, NY: McGraw-Hill (2000). p. 21–2 (2000).
 33. Nielsen J, Landauer TK. A mathematical model of the finding of usability problems. In: *Proceedings of ACM INTERCHI'93 Conference*. Amsterdam (1993). p. 206–13.
 34. Watters TS, Mather III RC, Browne JA, Berend KR, Lombardi AV Jr, Bolognesi MP. Analysis of procedure-related costs and proposed benefits of using patient-specific approach in total knee arthroplasty. *J Surg Orthopaed Adv*. (2011) 20:112–6.
 35. Bea FX, Göbel E. *Organisation – Theorie und Gestaltung*. Stuttgart: Lucius und Lucius (1999). p. 27–41.
 36. *The German Code of Ethics Refers to the Musterberufsordnung MBO § 15*. Available online at: www.bundesaerztekammer.de/recht/berufsrecht/muster-berufsordnung-aerzte/muster-berufsordnung/ (accessed September 23, 2019).
 37. Medical Device Regulation, EU 2017/745.
 38. *Medizinproduktegesetz (MPG), BVMed – Bundesverband Medizintechnologie e.V.* Berlin (2014).
 39. *European Medical Device Regulation*. Available online at: <http://data.europa.eu/eli/reg/2017/745/oj> (accessed September 23, 2019).
 40. Available online at: <https://wirtschaftslexikon.gabler.de/definition/direct-costing-29646/version-253247> (accessed September 24, 2019).
 41. Kenton W. *Opportunity Costs*. Investopedia. (2019). Available online at: www.investopedia.com (accessed October 03, 2019).
 42. Institut für das Entgeltsystem im Krankenhaus. *InEK Datenportal*. (2019). Available online at: www.g-drug.de/InEK_Datenportal (accessed September 23, 2019).
 43. von Eiff MC, von Eiff W. Qualität im medizinbetrieb. Ziele, dimensionen, bewertungskriterien und erfolgskriterien. In: Busch H-P, editor. *Qualitätsorientiertes Krankenhausmanagement*. Düsseldorf: Deutsche Krankenhaus Verlagsgesellschaft (2018). p. 55–79.
 44. Kasch R, Merk S, Drescher W, Schulz AP, Kayser R, Skribitz R, et al. Marginal contribution of UKS- versus TKA in varus arthrititis of the knee. *Arch Orthop Trama Surg*. (2012) 132:1165–72. doi: 10.1007/s00402-012-1535-2
 45. Berry ABL, Butler KA, Harrington C, Braxton MO, Walker AJ, Pete N, et al. Using conceptual work products of health care to design health IT. *J Biomed Informatics*. (2016) 59:5–30. doi: 10.1016/j.jbi.2015.10.014
 46. Available online at: www.businessdictionary.com (accessed October 04, 2019).

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Trends in Shared Decision-Making Studies From 2009 to 2018: A Bibliometric Analysis

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Background: To systematically analyze the global development trends and research focuses of shared decision-making (SDM) studies as a reference for researchers.

Methods: We conducted a systematic search of the Web of Science (WoS) Core Collection on April 17, 2019, to retrieve studies related to SDM published from 2009 to 2018. VOSviewer (1.6.10), CiteSpace (5.4.R1) and Excel 2016 were used to analyze key features of SDM studies, including annual output, countries/regions, organizations, journals, authors, references, research hot-spots, and frontiers.

Results: Up to April 17, 2019, a total of 6,629 studies on SDM were identified as published between 2009 and 2018. The United States participated in the most studies ($n = 3,118$), with the University of California-San Francisco ranking first ($n = 183$). *Patient Education and Counseling* [impact factor (IF) 2017 = 2.785] published the most studies ($n = 257$). Legare F participated in the most studies ($n = 101$), and the paper “Charles C, 1997, Soc Sci Med, V44, P681” occupied the highest co-citation ($n = 657$) position. The research hotspots and frontiers included “Informed consent,” “Surgery,” “Depression,” “Older adult,” and “Patient-centered care.”

Conclusion: The number of studies concerning SDM has continued to increase since 2009, with the United States leading the field. The landscape of the basis of SDM included mainly concept, practice framework and effect assessment of SDM. “Informed consent,” “Surgery,” “Depression,” “Older adult,” and “Patient-centered care” reflected the latest research focuses, and should receive more attention.

Keywords: shared decision-making, VOSviewer, CiteSpace, surgery, bibliometric analysis

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INTRODUCTION

Evidence-based medicine revolves around the concept that all decision-making regarding health should be based on best clinical evidence available, while emphasizing clinician experience and patient preferences and values (1, 2). When there are several alternatives, the patient's choice may determine the final treatment plan (3). Shared decision-making (SDM) is a new practical model applied to the field of healthcare that refers to clinicians working together with patients to make all decisions related to their health, including prevention, diagnosis, and treatment of conditions based on available evidence (4, 5). Several studies have showed SDM's advantages; for example, a Cochrane review (6) of more than 100 trials showed that SDM led to better outcomes in the decision-making and post-decision processes, as well as the intervention effect. In addition to

improving clinical outcomes, SDM can reduce medical costs (7). Therefore, close cooperation between clinicians and patients in the development of treatment options is highly beneficial (8).

Bibliometric analysis is a scientific method that combines statistical methods with information visualization technology to identify core entities, development trends and research focuses of specific subjects or research domains. A variety of software is available that can be used for bibliometric analysis, such as VOSviewer (9) and CiteSpace (10, 11). Recently, this method has been widely employed to conduct scientometric reviews (9, 10). For example, Qiu et al. (9) employed VOSviewer to review the evolutionary process of osteoporosis in post-menopausal women. This analysis showed a gradual shift in the research focus to precision medicine-orientated “basic research.” Using CiteSpace to analyze the development trends and research frontiers in the field of Alzheimer’s disease, Liu et al. (10) identified biomarkers and diagnostic criteria as the main focuses of Alzheimer’s disease research.

In an analysis of publication trends of the top 15 high impact medical journals from 1996 to 2011 conducted in 2014, Blanc et al. (12) showed an exponential increase in SDM-related publications. However, this study had a number of limitations. First, the study focused on a relatively small number of high impact medical journals; therefore, important papers published in general journals may have been overlooked. Second, this study focused mainly on scientific outputs, which may limit the implications for researchers. Third, although this study was published in 2014, the analysis focused only on the period from 1996 to 2011, and so did not include any more recent findings that may have been available. Therefore, we employed the VOSviewer and CiteSpace to conduct a new bibliometric study of SDM articles and reviews indexed in the Web of Science (WoS) Core Collection as a dataset to map the global trends and research focuses in the field of SDM.

MATERIALS AND METHODS

Data Sources

We conducted a comprehensive search of the WoS database on April 17, 2019, at Lanzhou University, Lanzhou, Gansu, China. To identify the recent developments, the timespan was set from January 1, 2009 to December 31, 2018. To ensure the representativeness of included studies, the types of publications were limited to “article” and “review.” The search strategy was as follows: Topic = “shared decision making” OR “informed decision making” OR “shared medical decision making” OR “informed medical decision making.” To avoid bias, all hits were downloaded as txt-format files from WoS on April 17, 2019 for further analysis.

Statistical Analyses

The WoS and VOSviewer (1.6.10) (9) were used to analyze key features (annual output, countries/regions, organizations, journals, impact factor (IF), authors, and references) of the SDM-related studies retrieved on April 17, 2019. VOSviewer was used to construct a network map of countries/regions, organizations,

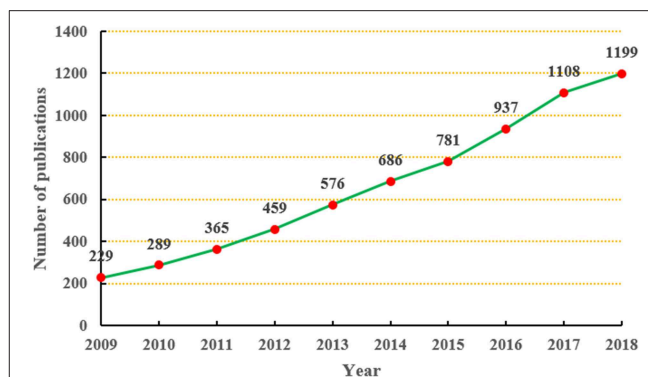


FIGURE 1 | Annual output of shared decision-making studies.

authors, and references, respectively. CiteSpace (5.4.R1) (10, 11) was used to construct dual-map overlay of journals and explore keywords with strong burst strength. Excel (Microsoft 2016, WA, USA) was used to manage data, create other charts and all data tables. The VOSviewer settings were as follows: counting method (full counting), while, thresholds (T) of items (countries/regions, organizations, authors, and references) were adopted based on special situations. The parameters of CiteSpace were as follows: link retaining factor (LRF = 2), look back years (LBY = -1), e for top N (e = 2), time span (2009–2018), years per slice (1), links (strength: cosine, scope: within slices), selection criteria (Top 50).

RESULTS

Annual Output

In total, we retrieved 6,629 SDM-related studies published from 2009 to 2018; therefore, the average annual output was 662.9. In the 2009, only 229 studies were published; however, 10 years later in 2018, the annual output reached 1,199. As shown in **Figure 1**, the annual output related to SDM research showed an obvious upward trend during the period from 2009 to 2018.

Analysis of Countries and Organizations

The top 10 countries and organizations participating in SDM studies are presented in **Table 1**.

As shown in **Figure 2A**, each country participated in at least 144 studies related to SDM. Moreover, six (United States, England, Canada, Netherlands, Australia, and Germany) of these countries participated in at least 506 studies. Furthermore, close cooperation was observed between of these countries. Among them, the United States participated in the most studies ($n = 3,118$), followed by England ($n = 742$), Canada ($n = 694$), and Netherlands ($n = 574$).

As shown in **Figure 2B**, every organization participated in at least 118 studies related to SDM, with four (University of California-San Francisco, Mayo Clinic, University of Sydney and University of Washington) participated in at least 143

studies. Furthermore, close cooperation was observed between several organizations, such as the University of Ottawa and the University of Laval, McMaster University and the University of Toronto, Radboud University Nijmegen and Cardiff University, and the University of California-San Francisco and Mayo Clinic. Among them, the University of California-San Francisco ranked first, participating in 183 studies, followed by Mayo Clinic ($n = 176$) and the University of Sydney ($n = 158$).

Analysis of Journals

The top 10 journals publishing SDM studies are presented in **Table 2**. These 10 journals totally published a combined total of 915 studies related to SDM, representing $\sim 14\%$ of all 6,629 studies retrieved. Three journals (*Patient Education and Counseling*, *Health Expectations* and *PLoS ONE*) published at least 90 studies each (257, 115, and 90, respectively). In terms of IF, all 10 journals were ranked from 1.733

(*Patient Preference and Adherence*) to 4.345 (*Implementation Science*), with an average IF value of 2.721. **Figure 3** shows the four citation paths. The two green paths indicate, articles published in medicine/medical/clinical journals cited journals mainly in the fields of molecular/biology/genetics and health/nursing/medicine. The other two pale blue paths indicate, articles published in psychology/education/health journals cited journals mainly in the fields of health/nursing/medicine and psychology/education/social.

Analysis of Authors and References

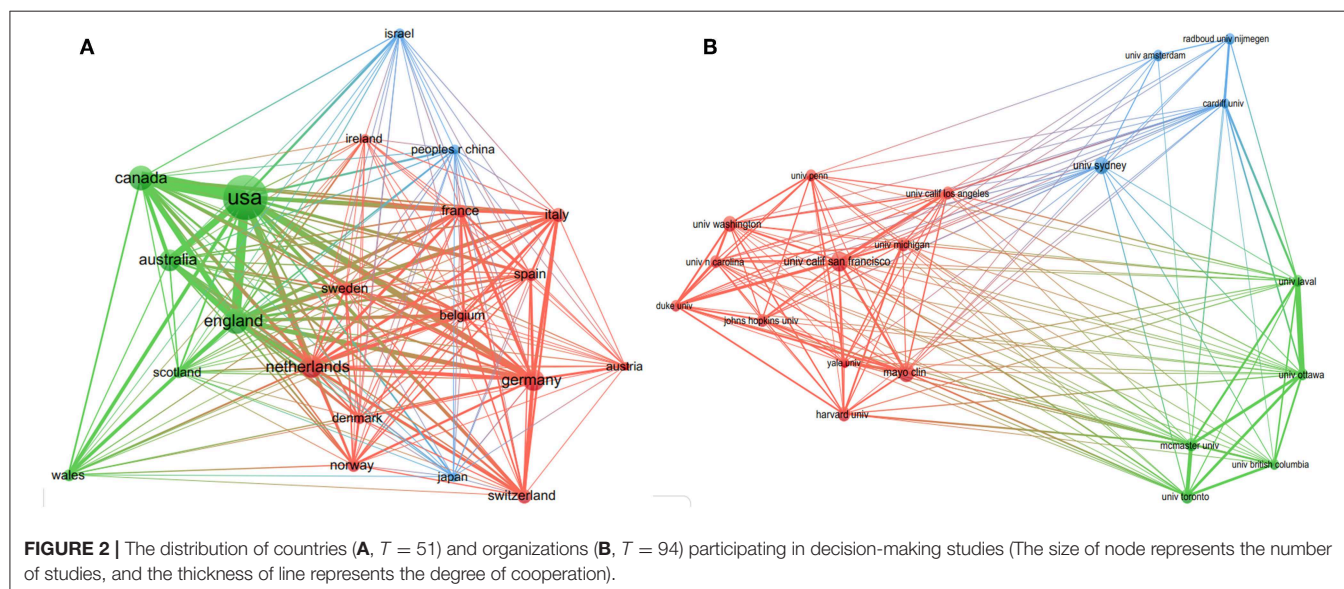
The top 10 authors and co-cited references of SDM studies are presented in **Table 3**. As shown in **Figure 4A**, every author participated in at least 26 studies related to SDM; with three (Legare F, Elwyn G and Stacey D) who participated in at least 59 studies. Furthermore, close cooperation was observed between several authors, such as Legare F and Stacey D, Labrecque M and Legare F, Montori VM and Leblanc A, and Elwyn G, and

TABLE 1 | The top 10 countries and organizations participating in shared decision-making studies.

Rank	Country/Region	Count	Organization	Count
1	United States	3,118	University of California-San Francisco	183
2	England	742	Mayo Clinic	176
3	Canada	694	University of Sydney	158
4	Netherlands	574	University of Washington	143
5	Australia	516	Harvard University	136
6	Germany	506	University of Toronto	132
7	Italy	175	University of Michigan	130
8	Switzerland	171	McMaster University	120
9	France	148	University of North Carolina	119
10	Spain	144	University of California-Los Angeles	118

TABLE 2 | The top 10 journals publishing shared decision-making studies.

Rank	Journal	Count	IF†2017
1	Patient Education and Counseling	257	2.785
2	Health Expectations	115	2.173
3	PloS One	90	2.766
4	Medical Decision Making	83	3.012
5	BMJ Open	71	2.413
6	BMC Health Services Research	70	1.843
7	Implementation Science	63	4.345
8	BMC Medical Informatics and Decision Making	61	2.134
9	Patient Preference and Adherence	53	1.733
10	Journal of General Internal Medicine	52	4.005

[†] *IF, Impact Factor.*

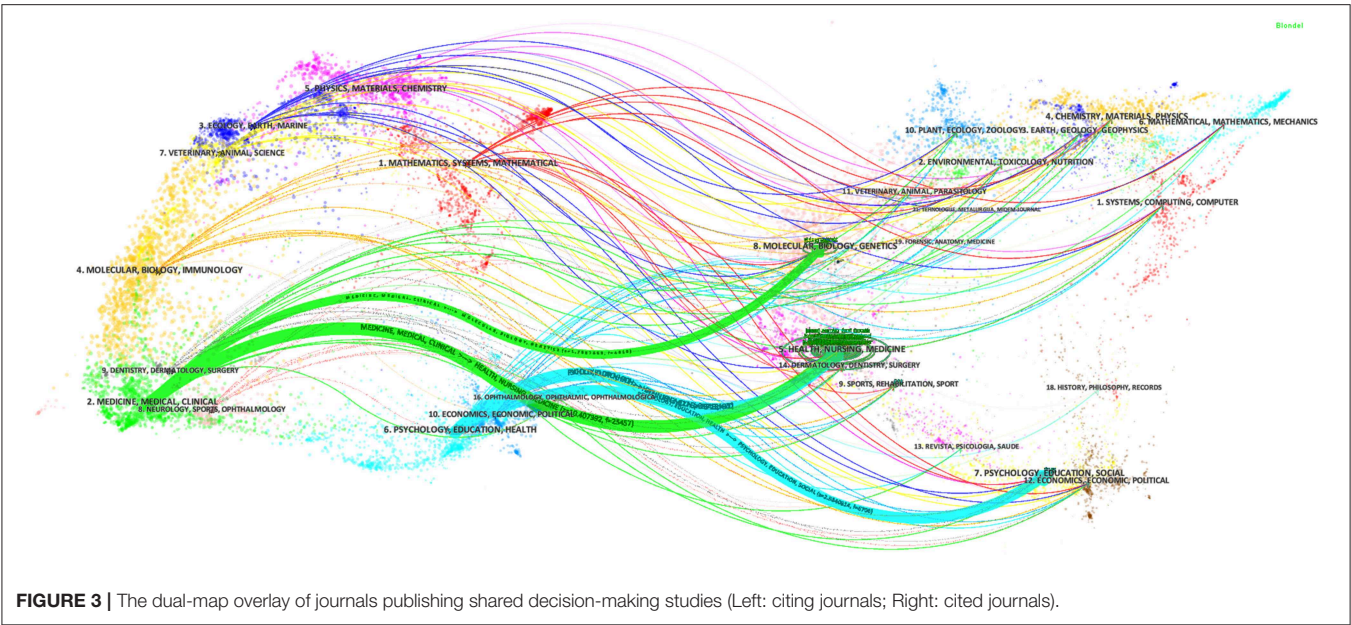


TABLE 3 | The top 10 authors and co-cited references of shared decision-making studies.

Rank	Author	Count	Co-cited reference	Count
1	Legare F	101	Charles C, 1997, Soc Sci Med, V44, P681 (13)	657
2	Elwyn G	84	Charles C, 1999, Soc Sci Med, V49, P651 (14)	334
3	Stacey D	59	Elwyn G, 2012, J Gen Intern Med, V27, P1361 (4)	319
4	Montori VM	53	Barry MJ, 2012, New Engl J Med, V366, P780 (15)	312
5	Leblanc A	33	Makoul G, 2006, Patient Educ Couns, V60, P301 (16)	312
6	Haerter M	31	Legare F, 2008, Patient Educ Couns, V73, P526 (17)	244
7	Labrecque M	28	O'Connor AM, 1995, Med Decis Making, V15, P25 (18)	239
8	Hess EP	27	Elwyn G, 2006, BMJ, V333, P417 (19)	236
9	Frosch DL	26	Joosten EA, 2008, Psychother Psychosom, V77, P219 (20)	200
10	Van Der Weijden T	26	Braddock CH, 1999, JAMA, V282, P2313 (21)	192

Edwards A. Among them, Legare F ranked first in terms of the number of studies contributed ($n = 101$), followed by Elwyn G ($n = 84$) and Stacey D ($n = 59$). In terms of co-cited references, each reference was cited at least 192 times, with five [“Charles C, 1997, Soc Sci Med, V44, P681” (13), “Charles C, 1999, Soc Sci Med, v49, P651” (14), “Elwyn G, 2012, J Gen Intern Med, V27, P1361” (4), “Barry MJ, 2012, New Engl J Med, V366, P780” (15), “Makoul G, 2006, Patient Educ Couns, V60, P301” (16)] being cited at least 312 times. Furthermore, several references,

such as “Charles C, 1997, Soc Sci Med, V44, P681” (13), “Charles C, 1999, Soc Sci Med, v49, P651” (14), and “Makoul G, 2006, Patient Educ Couns, V60, P301” (16), were cited by other articles simultaneously (Figure 4B).

Analysis of Keywords

The top 20 keywords with strong burst strength in SDM studies are presented in Table 4. The keywords with strong burst strength could represent research hotspots and frontiers (11). Using CiteSpace to explore keywords with strong burst strength, we found that these keywords covered many aspects of SDM, including “older adult” and “children;” “depression” and “schizophrenia;” “informed consent,” “surgery,” “patient participation” and “patient-centered care,” and “scale,” “framework” and “qualitative research.” In terms of burst strength, “Informed consent,” “Recommendation,” “Surgery,” “Patient participation” and “Depression” had higher ($N > 15$) burst strength. In terms of end-year, the five keywords comprised “Clinical practice” (2014–2018), “Surgery” (2015–2018), “Recommendation” (2016–2018), “Decision-making” (2016–2018), “Implementation” (2016–2018), and all were published in 2018 (Figure 5).

DISCUSSION

General Information

In this study, we conducted a bibliometric analysis to identify the core entities and map global trends and research focuses of SDM studies to provide a reference for researchers in this field.

We found a rapidly increasing trend in SDM studies published between 2009 and 2018, which is consistent with the findings of Blanc et al. (12) Among the top 10 countries/regions, the United States ($n = 3,118$) participated in by far the most papers and had an absolute advantage in terms of the number of studies,

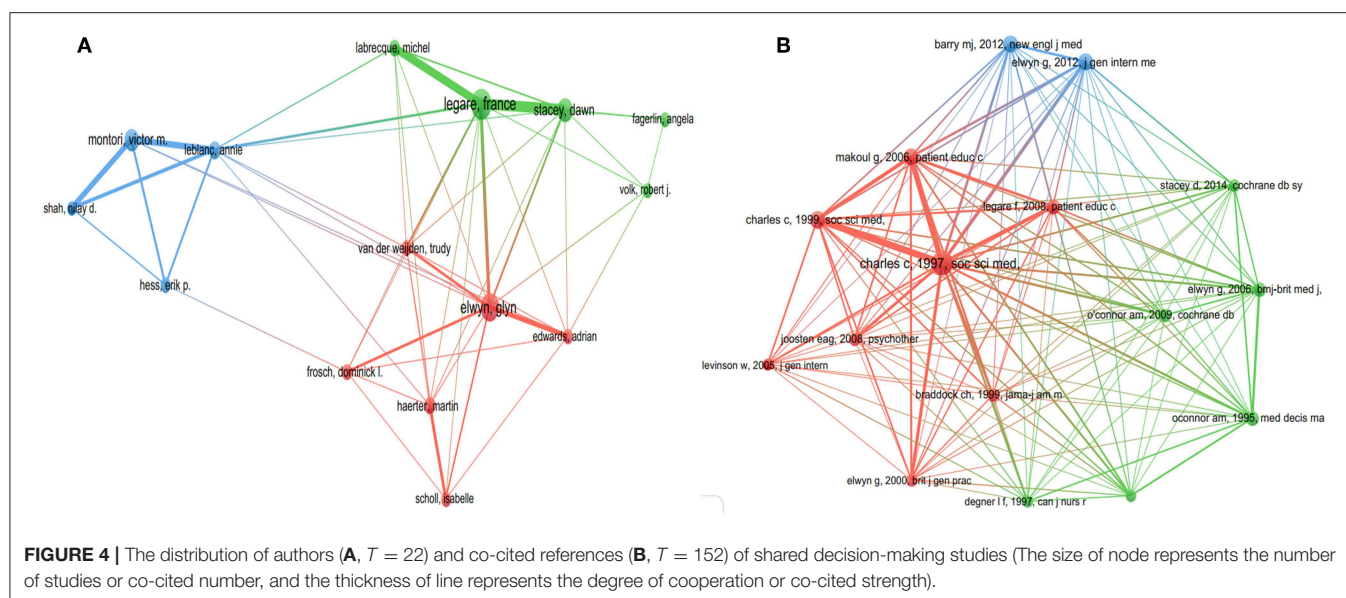


TABLE 4 | The top 20 keywords with strong burst strength in shared decision-making studies.

Rank	Keyword	Strength	Rank	Keyword	Strength
1	Informed consent	21.5221	11	Encounter	11.2492
2	Recommendation	21.4974	12	Clinical practice	10.8262
3	Surgery	18.1437	13	Patient-centered care	10.6406
4	Patient participation	15.9764	14	Informed decision making	10.6184
5	Depression	15.9764	15	General practice	10.2996
6	Decision-making	14.7794	16	Behavior	9.179
7	Scale	14.514	17	Schizophrenia	8.8003
8	Older adult	13.6693	18	Therapy	8.4503
9	Implementation	13.3161	19	Framework	8.1738
10	Choice	11.2625	20	Qualitative research	7.9773

followed by several other countries from Western countries, such as England ($n = 742$) and Canada ($n = 694$). Meanwhile, there was also close cooperation between these countries. The possible reasons for this result are, their medical concepts and technology are often in the leading position in the world, and they have a profound knowledge accumulation. Among the top 10 organizations, the University of California-San Francisco ($n = 183$) and Mayo Clinic ($n = 176$) participated in the most papers, ranking first and second, respectively. Furthermore, among the top 10 organizations, two (University of Toronto, McMaster University) were from Canada, one (University of Sydney) was from Australia, and all the rest were located in the United States. There was also a high degree of cooperation between the organizations, such as McMaster University and the University of Toronto, and the University of California-San Francisco and Mayo Clinic. In relation to the top 10 journals, *Patient Education and Counseling* ($n = 257$, IF2017 = 2.785)

and *Health Expectations* ($n = 115$, IF2017 = 2.173) published the most papers, ranking first and second. *Implementation Science* ($n = 63$, IF2017 = 4.345) had the highest IF, while the IFs of *Patient Education and Counseling* and *Health Expectations* ranked in only a medium position. Moreover, most of the journals focused on public health or medicine, and usually cited papers from the fields of health or social science. Among the top 10 authors, Legare F ($n = 101$), Elwyn G ($n = 84$), and Stacey D ($n = 59$) ranked first, second, and third, respectively, and we found close cooperation between Legare F and Stacey D. Moreover, Legare F and Elwyn G were authors of the most co-cited documents (4, 17, 19). These results can provide guidance for beginners in this field to cooperate with other entities, and submit their manuscripts.

Intellectual Base

A document co-citation network represents how frequently two studies are cited together by other papers (10, 11). These co-cited studies could be regarded as intellectual base of a special field or subject, which is also known as knowledge base (10, 11). Thus, we focused on the top 10 co-cited studies to evaluate the intellectual base related to SDM.

The most cited study with the highest number of co-citations ($n = 657$) was published in 1997 by Charles et al. (13). This study provided a clearer definition of SDM by identifying the following four key features: (1) two objects (clinician and patient) must be involved; (2) they should share information that they have; (3) they should reach a consensus based on treatment preference; and (4) reaching consensus on the treatment to practice. The second most cited paper received 334 co-citations, and also was published by Charles et al. (14), this paper revisited their framework on SDM, and raised decision-making approaches between three predominant models of SDM. The third most cited paper was published in 2012 by Elwyn et al. (4), with 319 co-citations. This paper proposed a specific three-step model of practice SDM, involving introduction of choice, description

Top 25 Keywords with the Strongest Citation Bursts

Keywords	Year	Strength	Begin	End	2009 - 2018
informed consent	2009	21.5221	2012	2015	
recommendation	2009	21.4974	2016	2018	
surgery	2009	18.1437	2015	2018	
patient participation	2009	15.9764	2012	2013	
depression	2009	15.9764	2012	2013	
decision-making	2009	14.7794	2016	2018	
scale	2009	14.514	2010	2011	
older adult	2009	13.6693	2015	2016	
implementation	2009	13.3161	2016	2018	
choice	2009	11.2625	2009	2014	
encounter	2009	11.2492	2009	2010	
clinical practice	2009	10.8262	2014	2018	
patient-centered care	2009	10.6406	2015	2016	
informed decision making	2009	10.6184	2014	2015	
general practice	2009	10.2996	2009	2010	
behavior	2009	9.179	2009	2012	
schizophrenia	2009	8.8003	2012	2013	
therapy	2009	8.4503	2009	2011	
framework	2009	8.1738	2013	2014	
qualitative research	2009	7.9773	2009	2010	
perspective	2009	7.9517	2012	2015	
children	2009	6.8778	2013	2014	
support	2009	6.3915	2010	2012	
prostate cancer	2009	6.1604	2009	2012	
trial	2009	5.8412	2009	2011	

FIGURE 5 | The citation burst of keywords in shared decision-making studies.

of alternatives, and helping patients to explore their preference and aid in their decision-making. The fourth most cited study, with 312 co-citations, was published in 2012 by Barry et al.

(15). These authors proposed that SDM as the central tenet of patient-centered care was long overdue, and recommended that clinicians should view the healthcare experience through their

patient's eyes. Makoul and Clayman (16) published the fifth most cited study in 2006, with 312 co-citations. This systematic review determined the range of SDM definitions, and eventually, an interactively conceptual definition was outlined. Legare et al. published the sixth most cited paper (17) in 2008, with 244 co-citations. This article reported an updated systematic review aiming to identify the barriers and facilitators associated with the implementation of SDM in clinical practice based on the opinions of health professionals regarding knowledge, attitudes and behaviors, such as inadequate awareness applicability, motivation, and communication. O'Connor (18) published the seventh most commonly co-cited paper, which reported the acceptability if using psychometric properties of the decisional conflict scale for application in SDM. Elwyn et al. (19) published the eighth most commonly co-cited paper, which reported the development of quality criteria for decision aids using the Delphi method. The authors established a quality criterion framework containing 12 unique domains. Joosten et al. (20) published the ninth most commonly co-cited paper, describing a systematic review of the effects of SDM on patient outcomes. This group found that SDM had no significant impact on patient outcomes in the short-term and suggested that future studies should focus on long-term decisions. Braddock et al. (21) published the tenth most commonly co-cited paper, reporting an evaluation of the nature and completeness of informed decision making in a cross-sectional study including 1,057 patients and 59 clinicians. These authors reported inadequacies in the efforts to encourage informed decision-making in clinical practice. Overall, we found that the top 10 co-citations focused mainly on aspects, such as concept or definition, practice framework or steps, and effect assessment of SDM, all which are the foundations of SDM research.

Research Hotspots and Frontiers

The keywords with strong burst strength are implicated as those that are paid special attention by scientific community during a specific time-period, and could therefore represent research hotspots and frontiers of a special field or subject in one period (11). Therefore, five phrases with higher burst were selected for in-depth analysis: "Informed consent," "Surgery," "Depression," "Older adult," and "Patient-centered care."

"Informed consent" is a dynamic process used to build mutual trust, in which the clinicians communicate with the patients to ensure that the patients know his or her own treatment decisions, and it usually includes oral communication and text material (22). A cross sectional study showed that age and level of education may influence the adequacy of written informed consent for surgical patients (22). Especially, a recent article (23) highlighted that the concept of traditional "Informed Consent" is evolving to match the requirements of the relatively new era of SDM.

"Surgery," which usually refers to manipulations implemented for the correction of abnormal conditions, repair of injuries, and treatment of particular diseases, is a complex and potentially dangerous intervention (24). It has been estimated that ~234.2 million surgical operations are performed every year worldwide (24). The efficiency of surgery is often influenced by a number

of factors, such as the surgeon's level of experience, decision-making, teamwork and environment (25). Therefore, informed consent and SDM are particularly critical in surgery. Efforts have been made to improve the communication and reporting of informed consent in surgery. For example, a current project (26) is underway to develop a core outcome set to improve reporting of outcomes and consent processes. A systematic review to identify features of SDM in surgery conducted by de Mik et al. (27) showed that surgeons and patients both recognized SDM, although SDM in surgery is in its infancy. Therefore, strategies to effectively practice and assess SDM in surgery are particularly important.

"Depression" is a common and heterogeneous condition with a chronic and recurrent natural course, that usually influences psychosocial functions and lowers quality of life of suffers (28). And according to the report from World Health Organization in 2017, there are more than 300 million people, or 4.4% of the global population (28). The high prevalence of depression leads to an enormous social and economic burden; therefore, strategies to control its occurrence are particularly important. A cluster randomized trial (29) including 117 clinicians and 301 patients showed that SDM improved the process of decision-making and the quality of primary care for patients with depression. Similarly, an uncontrolled cohort study (30) showed that SDM improved the process of decision-making and reduced depression symptoms in young patients.

"Older adult" is a special patient group that is often affected by multimorbidity. This group is increasing in size with the aging population and represents a huge social burden (31). In a cross-sectional investigation (32), SDM was shown to offer an approach to orthopedic care that is highly consistent with the preferences of older patients. SDM is regarded as a fundamental component of "Patient-centered care" (33). Ironically, despite the current information explosion, most patients have insufficient information about their condition and corresponding interventions for a variety of reasons. In 2013, the Institute of Medicine (IOM) found that cancer patients and their families could not fully understand adequate information to make informed decisions about their care in the United States, and highlighted the need for better patient-clinician communication and improved care coordination for this situation (34). Elwyn et al. (35) hypothesized that different methods of patient-centered care are needed depending on various clinical situations, and proposed a combination of motivational interviewing and SDM to achieve patient-centered care based on the patient's preferences and values.

Strengths and Limitations

The present study comprehensively analyzes the global trends and status of SDM research over the past decade by using the scientific method of bibliometric analysis. We systematically searched the WoS, and downloaded all relevant data on the same day. The core countries/regions, organizations, authors, journals, and research focuses were then identified to provide reference for scientists in the SDM field.

However, our study has some limitations like other scientometric studies. Firstly, we searched only the WoS,

and other large databases such as PubMed, EmBase and Scopus were not included, which may lead to the omission of some important studies from the present dataset. However, most published key papers are included in the WoS database, and moreover, the WoS is the most commonly used database in bibliometrics analysis (9, 10). Secondly, all datasets were identified using computer software or tool, such as VOSviewer, CiteSpace, and WoS, rather than being selected and collected manually, and manual selection and collection of datasets is required for systematic reviews or overviews (36–40); therefore, these datasets may be subject to bias (e.g., irrelevant studies may be included), although this would not affect the trends identified and conclusions of the present study. Finally, data generated from studies published in the current year (2019) were not included in our analysis as the dataset for this year is incomplete.

CONCLUSION

In the present bibliometric study, we identified a continual increase in the number of SDM-related studies since 2009, with the United States leading the field. *Patient Education and Counseling* was the core journal and Legare F was the most

active author. The landscape of the basis of SDM included mainly concept, practice framework and effect assessment of SDM. “Informed consent,” “Surgery,” “Depression,” “Older adult,” and “Patient-centered care” reflected the latest focuses, and should receive more attention.

DATA AVAILABILITY STATEMENT

The data used to support the findings of this study can be requested from the corresponding author.

AUTHOR CONTRIBUTIONS

KY and CL designed this study. CL and XL ran search strategy, collected data, and performed analyses. KY re-checked. CL wrote the manuscript. KY, CL, and XL reviewed the manuscript.

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REFERENCES

- Djulfbegovic B, Guyatt GH. Progress in evidence-based medicine: a quarter century on. *Lancet*. (2017) 390:415–23. doi: 10.1016/S0140-6736(16)31592-6
- Yao L, Sun R, Chen YL, Wang Q, Wei D, Wang X, et al. The quality of evidence in chinese meta-analyses needs to be improved. *J Clin Epidemiol*. (2016) 74:73–9. doi: 10.1016/j.jclinepi.2016.01.003
- Fredriksson M, Eriksson M, Tritter J. Who wants to be involved in health care decisions? Comparing preferences for individual and collective involvement in England and Sweden. *BMC Public Health*. (2017) 18:18. doi: 10.1186/s12889-017-4534-y
- Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med*. (2012) 27:1361–7. doi: 10.1007/s11606-012-2077-6
- Ruiz Yanzi MV, Barani MS, Franco JVA, Vazquez Peña FR, Terrasa SA, Kopitowski KS. Translation, transcultural adaptation, and validation of two questionnaires on shared decision making. *Health Expect*. (2019) 22:193–200. doi: 10.1111/hex.12842
- Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. (2017) 4:CD001431. doi: 10.1002/14651858.CD001431.pub5
- Oshima Lee E, Emanuel EJ. Shared decision making to improve care and reduce costs. *N Engl J Med*. (2013) 368:6–8. doi: 10.1056/NEJMp1209500
- Pieterse AH, Stiggelbout AM, Montori VM. Shared decision making and the importance of time. *JAMA*. (2019) 322:25–6. doi: 10.1001/jama.2019.3785
- Qiu Y, Yang W, Wang Q, Yan S, Li B, Zhai X. Osteoporosis in postmenopausal women in this decade: a bibliometric assessment of current research and future hotspots. *Arch Osteoporos*. (2018) 13:121. doi: 10.1007/s11657-018-0534-5
- Liu S, Sun YP, Gao XL, Sui Y. Knowledge domain and emerging trends in Alzheimer's disease: a scientometric review based on citespace analysis. *Neural Regen Res*. (2019) 14:1643–50. doi: 10.4103/1673-5374.255995
- Chen CM. CiteSpace II: Detecting and visualizing emerging trends and transient patterns in scientific literature. *J Am Soc Inf Sci Technol*. (2006) 57:359–77. doi: 10.1002/asi.20317
- Blanc X, Collet TH, Auer R, Fischer R, Locatelli I, Iriarte P, et al. Publication trends of shared decision making in 15 high impact medical journals: a full-text review with bibliometric analysis. *BMC Med Inform Decis Mak*. (2014) 14:71. doi: 10.1186/1472-6947-14Y71
- Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med*. (1997) 44:681–92. doi: 10.1016/S0277-9536(96)00221-3
- Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Soc Sci Med*. (1999) 49:651–661. doi: 10.1016/S0277-9536(99)00145-8
- Barry MJ, Edgman-Levitan S. Shared decision making—pinnacle of patient-centered care. *N Engl J Med*. (2012) 366:780–1. doi: 10.1056/NEJMp1109283
- Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient Educ Couns*. (2006) 60:301–12. doi: 10.1016/j.pec.2005.06.010
- Legare F, Ratte S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decisionmaking in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns*. (2008) 73:526–35. doi: 10.1016/j.pec.2008.07.018
- O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. (1995) 15:25–30. doi: 10.1177/0272989X9501500105
- Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. (2006) 333:417. doi: 10.1136/bmj.38926.629329.AE
- Joosten EA, DeFuentes-Merillas L, de Weert GH, Sensky T, van der Staak CP, de Jong CA. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom*. (2008) 77:219–26. doi: 10.1159/000126073
- Braddock CH 3rd, Edwards KA, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA*. (1999) 282:2313–20. doi: 10.1001/jama.282.24.2313
- Agozzino E, Borrelli S, Cancellieri M, Carfora FM, Di Lorenzo T, Attena F. Does written informed consent adequately inform surgical patients? A cross sectional study. *BMC Med Ethics*. (2019) 20:1. doi: 10.1186/s12910-018-0340-z
- Slim K, Bazin JE. From informed consent to shared decision-making in surgery. *J Visc Surg*. (2019) 156:181–4. doi: 10.1016/j.jvisurg.2019.04.014

24. Yu J, Chen W, Chen S, Jia P, Su G, Li Y, et al. Design, conduct, and analysis of surgical randomized controlled trials: a cross-sectional survey. *Ann Surg.* (2019) 270:1065–9. doi: 10.1097/SLA.0000000000002860
25. Li N, Marshall D, Sykes M, McCulloch P, Shalhoub J, Maruthappu M. Systematic review of methods for quantifying teamwork in the operating theatre. *BJS Open.* (2018) 2:42–51. doi: 10.1002/bjs5.40
26. Convie LJ, McCain S, Campbell J, Kirk SJ, Clarke M. Evaluating interventions for informed consent for surgery (ICONS): protocol for the development of a core outcome set. *Trials.* (2018) 19:609. doi: 10.1186/s13063-018-2986-8
27. de Mik SML, Stubenrouch FE, Balm R, Ubbink DT. Systematic review of shared decision-making in surgery. *Br J Surg.* (2018) 105:1721–30. doi: 10.1002/bjs.11009
28. Ferencich EK, Ramanuj P, Pincus HA. Depression in primary care: part 1-screening and diagnosis. *BMJ.* (2019) 365:l794. doi: 10.1136/bmj.l794
29. LeBlanc A, Herrin J, Williams MD, Inselman JW4, Branda ME4, Shah ND5, et al. Shared decision making for antidepressants in primary care: a cluster randomized trial. *JAMA Intern Med.* (2015) 175:1761–70. doi: 10.1001/jamainternmed.2015.5214
30. Simmons MB, Elmes A, McKenzie JE, Trevena L, Hetrick SE. Right choice, right time: evaluation of an online decision aid for youth depression. *Health Expect.* (2017) 20:714–23. doi: 10.1111/hex.12510
31. Chang AY, Skirbekk VF, Tyrovolas S, Kassebaum NJ, Dieleman JL. Measuring population ageing: an analysis of the global burden of disease study 2017. *Lancet Public Health.* (2019) 4:e159–67. doi: 10.1016/S2468-2667(19)30019-2
32. Dardas AZ, Stockburger C, Boone S, An T, Calfee RP. Preferences for shared decision making in older adult patients with orthopedic hand conditions. *J Hand Surg Am.* (2016) 41:978–87. doi: 10.1016/j.jhsa.2016.07.096
33. Eliacin J, Salyers MP, Kukla M, Matthias MS. Patients' understanding of shared decision making in a mental health setting. *Qual Health Res.* (2015) 25:668–78. doi: 10.1177/1049732314551060
34. Nekhlyudov L, Levit L, Hurria A, Ganz PA. Patient-centered, evidence-based, and cost-conscious cancer care across the continuum: translating the institute of medicine report into clinical practice. *CA Cancer J Clin.* (2014) 64:408–21. doi: 10.3322/caac.21249
35. Elwyn G, Dehlendorf C, Epstein RM, Marrin K, White J, Frosch DL. Shared decision making and motivational interviewing: achieving patient-centered care across the spectrum of health care problems. *Ann Fam Med.* (2014) 12:270–5. doi: 10.1370/afm.1615
36. Chapman A, Liu S, Merkouris S, Enticott JC4, Yang H5, Browning CJ, et al. Psychological interventions for the management of glycemic and psychological outcomes of type 2 diabetes mellitus in China: A systematic review and meta-analyses of randomized controlled trials. *Front Public Health.* (2015) 3:252. doi: 10.3389/fpubh.2015.00252
37. Pan B, Ge L, Xun YQ, Chen YJ1, Gao CY1, Han X, et al. Exercise training modalities in patients with type 2 diabetes mellitus: a systematic review and network meta-analysis. *Int J Behav Nutr Phys Act.* (2018) 15:72. doi: 10.1186/s12966-018-0703-3
38. Chaudhary D, Sharma N, Senapati S. Serum homocysteine could be used as a predictive marker for chronic obstructive pulmonary disease: a meta-analysis. *Front Public Health.* (2019) 7:69. doi: 10.3389/fpubh.2019.00069
39. Xiu-xia L, Ya Z, Yao-long C, Ke-hu Y, Zong-jiu Z. The reporting characteristics and methodological quality of Cochrane reviews about health policy research. *Health Policy.* (2015) 119:503–10. doi: 10.1016/j.healthpol.2014.09.002
40. Tian J, Zhang J, Ge L, Yang K, Song F. The methodological and reporting quality of systematic reviews from China and the USA are similar. *J Clin Epidemiol.* (2017) 85:50–8. doi: 10.1016/j.jclinepi.2016.12.004

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Person-Centered Care From a Relational Ethics Perspective for the Delivery of High Quality and Safe Healthcare: A Scoping Review

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Background: The aim of this scoping review is to explore whether or not person-centered care (PCC), in its quest to deliver high quality and safe health care, has a relational-ethics perspective. To do so, we first need to relate the extant literature pertaining to PCC and relational ethics. To this extent, the specific features that define PCC and relational ethics were identified. PCC dimensions include: patient and provider concordance, improved health outcomes, improved patient safety, individual expectations, patients' integration within the environment, patient as a person, patient as an active part of society, dialogue and interaction, sharing experience, and documentation of patient's (person's) narrative. Relational ethics framework includes the following actions: mutual respect, engagement, embodied knowledge, environment, and uncertainty.

Methods: Data were retrieved through multiple keywords search on PubMed, Medline, and Scopus. Inclusion/exclusion criteria were set, and these were based on year of publication (2008–2018), language, paper focus, research method and document types. A total of 23 articles ($N = 23$) were selected and reviewed. Content analysis was conducted in order to identify and compare the main features of PCC and relational ethics.

Results: The most important relational ethics action referred to in conjunction with PCC features is environment (referred to as person's integration within a social environment/community). This is followed by mutual respect, engagement and embodied knowledge. These were the salient relational ethics actions both directly and indirectly linked to PCC. Uncertainty was the less recurrent relational ethical action mentioned.

Conclusions: This paper revealed that while PCC features embrace most of the relational ethics approaches, these are not exploited in their entirety and therefore PCC emerges as a unique ethical stance in healthcare. PCC's ethical approach goes beyond what is explained within provider-patient relational ethics and emphasizes that the patient is an active person and a partner in care with capabilities and resources.

This distinction enables us to explain the paradigm shift from “patient-centered” to “person-centered” care. The healthcare provider partnership and co-creation of the healthcare plan contributes to the delivery of high quality, safe and cost-contained healthcare.

Keywords: person-centered care (PCC), patient-centered care, ethics, relational ethics, patient safety, quality of care, health systems

BACKGROUND

Person-centered care (PCC) is a responsive and respectful approach to care taking into consideration persons’ demands, preferences, and principles (1). It contributes to patients’ empowerment by involving them in decision-making processes on treatment plans (2–4). In this respect, PCC is a development of the original concept of patient-centered care—which is defined in literature as “understanding the patient as a unique human being” (5). Patient-centered care is the most well-known concept in literature, however this approach considers the patient as a more passive recipient of care and its focus is merely on the medical treatment and diagnosis. PCC goes beyond patient-centered care as it has an ethical foundation and sees the person (not just the patient) as an active part of medical treatment and considers his/her needs, family, history, strengths and weaknesses. According to McWhinney and Stewart, who explored PCC outcomes within health systems (6), PCC sees the patient at the center of medical care, as well as of education and research (2003).

But it was Ekman et al. (7), who took PCC to a different and higher ethical level by basing their philosophy on Amartya Sen’s capability approach, namely that the person is considered as someone who has capacities or is capable (8–11). This approach finds its roots in Aristotle’s principle of human flourishing where quality is not an act, but it is a habit and healthcare providers are called to improve their emotional intelligence so as to be able to take care of other persons’ needs (12). Furthermore, Aristotle’s perspective of care assumed that each person has to be considered individually and as a special case. Persons not only have needs but they are repositories of capabilities and resources that can be engaged, and this is the point of departure in PCC. Thus, Ekman et al.’s philosophy of PCC (7), sees the patient as a capable human being, even if he or she is very weak or sick. Moreover, the patient with the healthcare provider/s are seen as partners in care and co-creators of the healthcare plan. According to Ekman et al., in order to create this partnership, health providers have to listen to the patients by taking into consideration their experiences, conditions and also individual expectations (13). A mutual health plan is to be agreed upon and has to be updated continuously and documented. Thus, responsibilities are equally distributed between the patient and the provider/s (14, 15).

According to Ekman et al. (7), PCC is characterized by three key concepts, namely: (i) person-provider partnership; (ii) inclusion of patient’s narrative; and (iii) documentation of patient’s (person’s) narrative. However, further components can be identified while describing PCC features. These include: patient and provider concordance; improved health outcomes;

TABLE 1 | Person-centered care features.

Person-centered care concepts	Features
Partnership	Patients and providers concordance Patients integration within the environment Patient as a person Patient as an active part of his/her healthcare and of society
Patient narrative	Individual expectations Dialogue and interaction Sharing experience
Documentation	Documentation Improved health outcomes Improved patient safety

improved patient safety; individual expectations; patients’ integration within the environment; patient as a person; patient as an active part of society; dialogue and interaction; sharing experience; documentation. **Table 1** summarizes PCC features according to Ekman et al. (7) framework.

In order to better understand PCC and implement this approach within healthcare organization, it needs to be considered from an ethical perspective, which lies in the healthcare principle of recognizing self-fragility and coherence in life (7, 16). Some authors sustain that PCC already embodies ethics within itself (17), considering that its foundations lie in the human relationship between patients and providers—which is based on the key consideration of patients as persons. Thus, the person is not considered individualistically but in relation with others and embodied, interdependent and connected with the social environment and context (18). This approach determines the paradigm shift from the biomedical model of care—which is characterized by the dominance of the physician—to the biopsychosocial model where the person takes a central role in the decision-making processes regarding medical treatments (19). In this regard, biochemical alterations are not the only determinants of illnesses, but they need to be considered together with psychosocial variables and the relationship between the patient and the professional (20) plays a key role in influencing medical outcomes (6, 21–23). According to this philosophy, a correct diagnosis is only partially dependent of the healthcare provider’s clinical tasks, which need to be complemented with proper dialogue and interaction with patients (24–26) in order to provide a more effective diagnosis (27). Thus, the ethical component represents a key aspect of PCC. Ethics refers to the principle of doing the right thing,

TABLE 2 | Relational ethics features (18).

Feature	Short description
Mutual respect	Refers to the responsibility to the others (patients).
Engagement	To establish an engaged relationship with others (patient-provider relationship).
Embodied knowledge	Getting to know patients' needs, preferences, values to guide and orientate decision-making processes (partnership and patients' narrative).
Environment	Refers to the relationship between the person and the context of the social environment (taking into account patients' needs, values, family, community, history).
Uncertainty	The difficulty of undertaking a course of action or making decisions due to value-based demands.

establishing the right kind of relationships and/or destroying what is wrong according to the basic concepts and fundamental principles of decent human conduct (28). Within the broad concept of ethics, the relational ethics theory assumes a key importance in the context of PCC. Building on Bergum and Dossetor (29) and Pollard (18), relational ethics refers to those relationships, which are considered better than others and aim at stimulating growth, healing, and health. Furthermore, according to Evans (30), relational ethics is defined as an action ethics that is placed within the interpersonal relationships. The action ethics includes engagement, mutual respect, embodiment, and interdependent environment. The leading principle is that ethical decisions and actions should be made in the context of relationships. According to this perspective, the focus of relational ethics is not the action itself but the relationship (31). Thus, the relational ethics framework includes the following actions: mutual respect; engagement; embodied knowledge; environment; and uncertainty [(18), p. 364]. These parameters should ensure that relations are established in the right way and lead to ethical decisions and actions. **Table 2** summarizes and explains relational ethics features according to Pollard (18).

As mentioned above, PCC seems not only to embody relational ethics but goes even beyond by assuming that persons are not only central to medical treatments, but they are at par with their providers, thereby strengthening even more the relationship aspect (7). This explains why PCC implies the paradigm shift from the notion of “patient-centered” to that of “person-centered.” The shift delineates that the patient is a person, a human being, with a unique background, relationships, capabilities, resources, strengths, and limitations.

Based on these assumptions, the aim of this scoping review is to explore whether or not PCC, in its quest to deliver high quality and safe health care, has a relational-ethics perspective. The research questions that guided this paper are: (i) to what extent is person-centered care related to relational ethics?; and (ii) what is the value of PCC as an ethical approach in delivering higher quality and safer healthcare?

The next sections of this paper will present: (i) the methodology and research strategy conducted for this review; (ii) results; and (iii) a discussion of results, main limitations of this study and further research directions.

METHODS

A scoping review was conducted to explore and understand the relation between PCC and relational ethics in the quest to deliver high quality and safe care in health care systems.

Scoping reviews are used to map concepts underpinning a research area and the main sources and types of evidence available. Scoping reviews are now seen as a valid approach in those circumstances where systematic reviews are unable to meet the necessary objectives or requirements of knowledge users. Due to lack of consistency existing in the terminology, definition, methods, and reporting of scoping reviews appearing in the literature, it is recommended to use PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement for the reporting scoping articles (32) (**Table 3**).

Methodology of this review followed the steps as below: (i) inclusion and exclusion criteria for selecting articles were first identified; (ii) a search strategy was decided upon common agreement between all authors involved in this study; (iii) databases and keywords were identified according to the theoretical framework upon which this review was based; and (iv) division of tasks for reviewing articles and data extraction tools were agreed.

Inclusion/Exclusion Criteria

Inclusion/exclusion criteria were established according to timespan, language, paper focus, research type, publication type, and research area. We searched for articles published from 1st January 2008 up to 30th November 2018 in order to include articles published in the last decade. We included only articles written in English, as it is the working language used by the authors involved in this study. Regarding papers' focus, we decided to include articles providing evidence on: (i) person-centered care; (ii) patient-centered care; and (iii) ethics/relational ethics person-centered care (or person-centered care). Papers not providing any of the aforementioned themes were excluded. Regarding research type, we included only papers based on primary search. We included in our databases search only papers/articles published in peer-reviewed journals, excluding website, documents, media articles, and other non-research documents since they do not offer research-based evidence. Furthermore, to avoid a large number of publications, we decided to exclude books and book chapters, dissertations, research reports, and conference proceedings. Finally, to avoid the inclusion of papers not pertinent to the aim of this paper, we considered only articles within the areas of: medicine; nursing; social sciences; psychology; health professions; biochemistry, genetics, and molecular biology; neuroscience; dentistry; pharmacology, toxicology and pharmaceuticals. Although we have considered to include papers within other fields, notably ethics, we wanted to stick to the perspectives emanating only from those specialties that provided explanations on person-centered care, which is our main focus.

Regarding types of studies, qualitative, quantitative, as well as mixed studies, literature reviews and commentaries were included. Furthermore, no geographical limitations were applied in the search strategy.

TABLE 3 | Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist.

Section	Item	PRISMA-ScR checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	1–4
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	4
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	N/A
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	4–5
Information sources	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	5
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	5
Selection of sources of evidence	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	5
Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	5
Critical appraisal of individual sources of evidence	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	N/A
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	N/A
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	6
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	6–8
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	N/A
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	6–8
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	6–8
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	8–9
Limitations	20	Discuss the limitations of the scoping review process.	9
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	10
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	11

From: *Tricco et al.* (32).

TABLE 4 | Inclusion/exclusion criteria and main justification.

Item	Inclusion criteria	Exclusion criteria	Main justification
Timespan	All articles from 2008 onwards	Articles published before 2008	Papers published in the last decade.
Language	Papers written in English	Papers not written in English	English is the working language of the reviewers
Paper focus	Papers which provide evidence on: <ul style="list-style-type: none"> • Person-Centered care • Patient-Centered care • Ethics/relational ethics 	Papers which do not provide evidence on person-centered care, patient-centered care, ethics/relational ethics.	This criterion is justified by the review questions
Research type	Papers based on primary research	Papers not based on primary research Opinion articles	This criterion is justified by the review questions
Publication type	Papers/articles published in peer-reviewed journals based on both theoretical and empirical research	Website documents, media articles and other non-research documents Books and book chapters, dissertations, research reports, conference proceedings	Website documents, media articles and other non-research documents were excluded because they do not offer research-based evidence Books and book chapters, dissertations, research reports, conference proceedings were excluded to avoid a large volution of publications
Research area	Papers within the areas of: medicine; nursing; social sciences; psychology; health professions; biochemistry, genetics and molecular biology; neuroscience; dentistry; pharmacology, toxicology and pharmaceutics;	Papers whose research area is different from the listed ones	To avoid the inclusion of papers not pertinent to aim of this work.

Table 4 illustrates inclusion and exclusion criteria adopted in this work.

Search Strategy

PCC and relational ethics were analyzed separately in order to identity their key features according to the literature as illustrated in **Table 2**. Upon reviewing the literature arising from the search, we elicited a framework for PCC and relational ethics features (**Tables 1, 2**).

This research was conducted using the following databases: Scopus, PubMed, and Medline. The choice of these databases was due to their consolidate reputation among research community.

The following combination of keywords was used to search in Scopus and Medline database search: “person-centered care” AND “mutual respect” OR engagement OR “embodied knowledge” OR environment OR uncertainty.

While searching articles in PubMed, since its software characteristics did not allow us to use the same strategy adopted in Scopus and Medline, we adopted the following combination of keywords: “person-centered care” AND “mutual respect”; “person-centered care” AND engagement; “person-centered care” AND “embodied knowledge”; “person-centered care” AND environment; “person-centered care” AND uncertainty.

Selection of Publications

The (PRISMA) flow diagram (33) illustrated in **Figure 1** shows the number of publications that were selected in the different phases of this scoping review and the final total of articles included.

Data Extraction and Synthesis

All articles were reviewed by all authors involved in this study, with an equal division of tasks. All relevant data contained in the reviewed articles were extracted to a data extraction form. The

final version of the data extraction form includes the following items: article number; reference; year; author(s); title; country, health service; setting; aim(s)/objective(s); research design; method; population/sample; findings; and constructs variables. Each selected paper was reviewed in view of determining whether the identified construct features/actions were directly or indirectly mentioned.

Results are presented as below: (i) the general results (results of search screening, number of articles per year, country, and methodology approach) are first presented; (ii) the matches between PCC features and relational ethics actions identified in reviewed articles are further analyzed and discussed; and (iii) article groups are finally identified according to their communalities with regard to the framework considered in this scoping review.

RESULTS

Results of this scoping review allowed us to explore the relationships between PCC features and relational ethics actions. The analysis of the findings of the review exercise enabled us to understand the PCC -relational ethics perspective. The relationship between direct and indirect PCC features and relational ethics actions were identified.

General Results

The searches in electronic databases yielded a total of 120 publications ($N = 120$). After removing 20 duplicates ($N = 20$), the total of published items to screen shifted to 100 ($N = 100$). After having applied the inclusion/exclusion criteria to titles and abstracts, 73 publications ($N = 73$) were excluded. Most of the screened publications were excluded because they were not pertinent to the research questions guiding this study

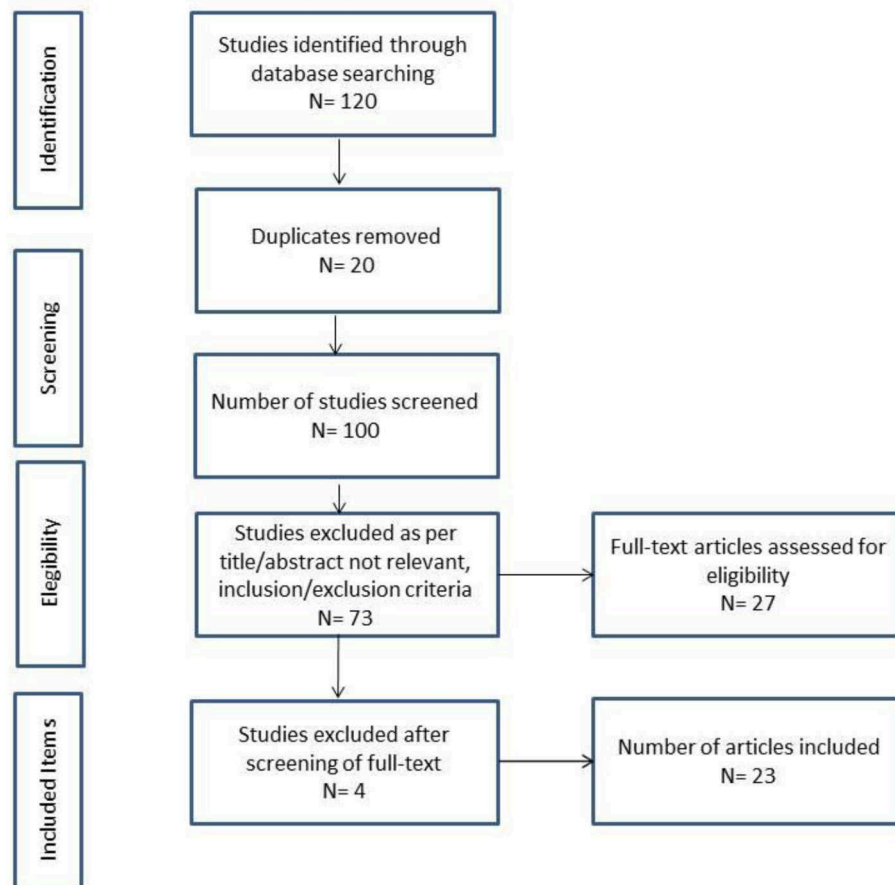


FIGURE 1 | PRISMA flow chart.

and/or because they were not research papers. Upon the full-text screening, 4 publications ($N = 4$) were excluded since they were not pertinent to the research conducted in this paper. At the end of the process, 23 articles ($N = 23$) were included in this review (**Figure 1**). Article details can be retrieved from **Supplementary Material** attached to this review according to author(s), year, direct and indirect relational ethics framework, and direct and indirect PCC framework.

Most of the reviewed articles were published from 2015 onwards with a relatively peak of publications ($N = 5$) in 2016. Most of the included papers were published in Sweden (26%), United States of America and United Kingdom (22%). The studies which were screened included both qualitative and quantitative studies, as well as mixed method research studies, literature reviews and commentaries. The majority of papers were qualitative (31%) and quantitative studies (26%), followed by mixed method studies (17%). The minority of papers were literature reviews and commentaries (13%).

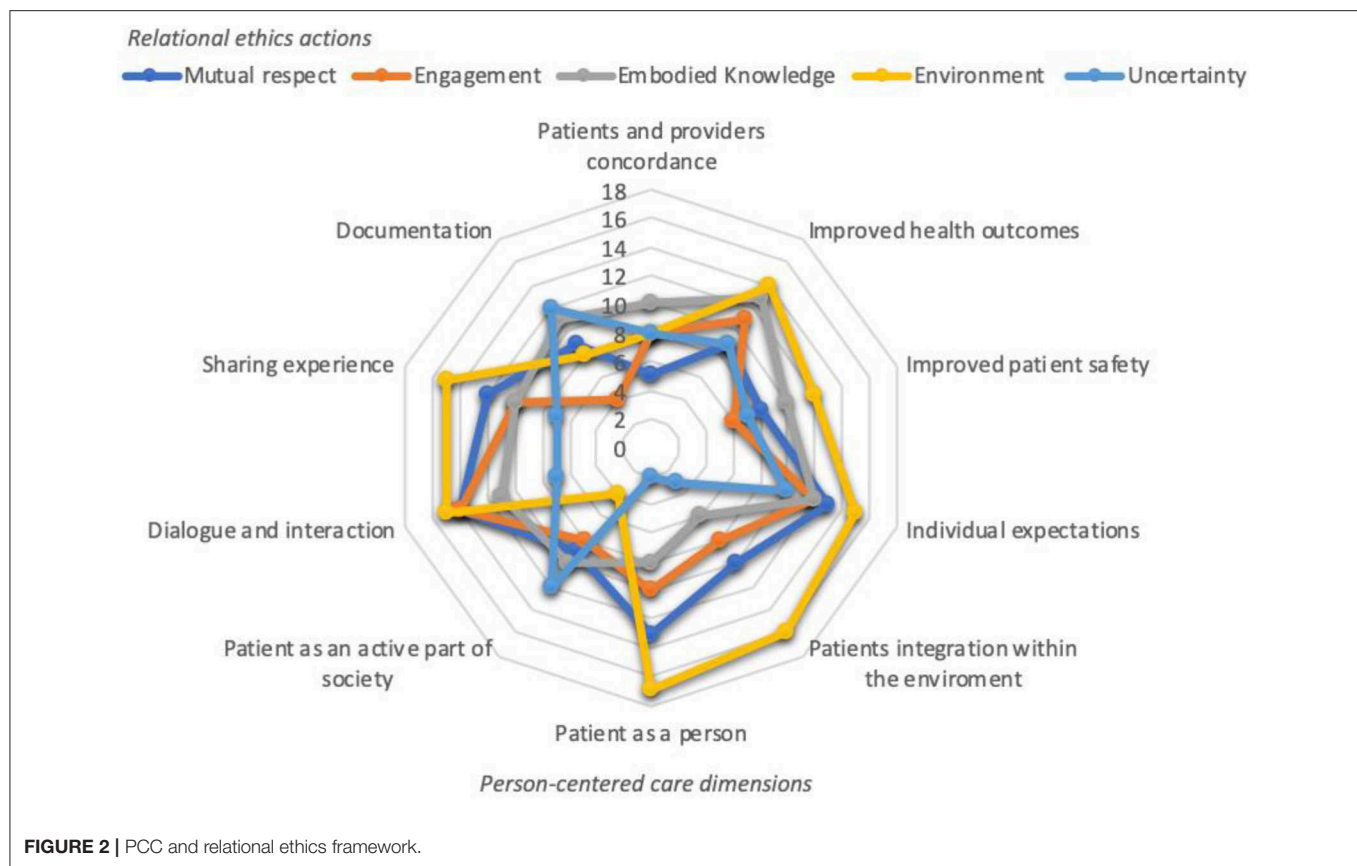
PCC and Relational Ethics

Findings of this scoping review revealed matches and congruences between PCC and relational ethics. By doing

so, we analyzed and compared PCC and relational ethics' dimensions that were mentioned (both directly and indirectly) in the reviewed papers (**Figure 2**).

As **Figure 2** illustrates, there is congruence between PCC and relational ethics. The relationship between the person and the context of the social environment was the most recurring relational ethics action that was mentioned in reviewed papers together with the different PCC features. However, PCC emphasizes the role of the patient to that of a unique person, as a partner in care, as a co-creator of his/her healthcare plan, and integrated within the environment—social and other that the person is connected to. This does not seem to be clearly accentuated in defining relationships as part of relational ethics. Nevertheless, patient as a person, patients' integration within the environment, individual expectations, dialogue and interaction, and sharing experience followed by improved health outcomes, and improved patient safety are the most frequently PCC features mentioned in that order together with the relational ethics action environment.

Relationships were also observed with regard to relational ethics actions of embodied knowledge, mutual respect, and engagement and PCC features of improved health outcomes,



improved patient safety, individual expectations, patient as an active part of society, dialogue and interaction, sharing experience, and documentation.

Uncertainty, namely the difficulty of undertaking a course of action or making decisions due to value-based demands, was the least stressed relational ethics action from Pollard's framework. It was sought to be related mostly to PCC features of improved health outcomes, individual expectations and documentation.

Article Groups

While analyzing the results of the 23 articles, we identified three groups of articles (Table 5) according to the framework taken into considerations. Group 1 is the largest one with 17 articles, followed by group 3 (3 articles) and group 2 (2 articles). Only one article (56) was identified as not representing none of the three groups.

As per Table 4, almost all PCC features and relational ethics actions were mentioned in articles belonging to group 1 (34–50).

In group 2 (51, 52), individual expectations, patients' integration within the environment, dialogue and interaction, improved patient safety, patient as a person, patient as an active part of society and sharing experience were the most recurring PCC features mentioned together with relational ethics actions of engagement, environment and uncertainty.

In group 3 (53–55), PCC features of patient as a person, individual expectations, patient as an active part of society

and documentation were mentioned in conjunction with relational ethics actions of environment, embodied knowledge and uncertainty.

Finally, in English (56)—which was not belonging to none of the aforementioned group—patients and providers' concordance, improved health outcomes, individual expectations, patient as a person, dialogue and interaction and sharing experience were mentioned together with relational ethics actions of mutual respect, engagement, uncertainty, and embodied knowledge.

DISCUSSION

Summary of Main Findings

Results emerging from the 23 articles included in this scoping review suggest that there is a notable relationship between PCC features and relational ethics actions. However, PCC seems to go beyond and raises the provider-patient relationship to a higher ethical approach, namely that partner in care and co-creator of the healthcare plan.

Nevertheless, the relevance of embodied knowledge, mutual respect, engagement and uncertainty within the caring environment was identified as the most recurrent relational ethical dimension in relation to the majority of PCC features.

Thus, there is certainly a match between PCC features and relational ethics dimensions as discussed in Pollard's framework.

TABLE 5 | Article groups.

Group	References	PCC	Relational ethics
1	Abbott et al. (34) Boscart et al. (35) Coyne et al. (36) Edvardsson et al. (37) Edvardsson et al. (38) Elfstrand Corlin et al. (39) Hung et al. (40) Alharbi et al. (41) Dudas et al. (42) Fawcett and Rhynas (43) Howard et al. (44) Johnston et al. (45) Kuluski et al. (46) Sjögren et al. (47) Stanhope et al. (48) McCormack et al. (49) Mills et al. (50)	Improved health outcomes Improved patient safety Individual expectations Dialogue and interaction Sharing experience Documentation Patients and providers concordance Patients integration within the environment Patient as a person Patient as an active part of his/her healthcare plan and of society	Mutual respect Embodied knowledge Environment Uncertainty Engagement
2	Geboy (51) Røsvik et al. (52)	Individual expectations Patients integration within the environment Dialogue and interaction Improved patient safety Patient as a person Patient as an active part of his/her healthcare plan and of society Sharing experience	Engagement Environment Uncertainty
3	Røen et al. (53) Rubashkin et al. (54) Scales et al. (55)	Patient as a person Individual expectations Patient as an active part of his/her healthcare plan and of society Documentation	Environment Embodied knowledge Uncertainty

If we look at the three pillars of PCC—partnership, patients' narrative, and documentation—we can sum up that the articles reviewed in this scoping review addressed these areas in almost their entirety, although only exclusively addressed by Ekman and her colleagues. The relationship between the two concepts stands in the assumption that while health professionals are establishing a partnership with their patients and listening to their stories, they are exercising an ethical behavior at the same time.

Furthermore, we can summarize communalities between PCC features and relational ethics actions. In this respect, the PCC feature of patient as a person is totally embraced by the relational ethics action of mutual respect. Treating patients as persons finds its ethical foundations in the mutual respect concept, which is referred to physicians' social and ethical responsibilities toward their patients. PCC pillars of partnership and patients' narrative can be connected to relational ethics actions of embodied knowledge and engagement. Getting to know patients' needs, preferences, values, as well as establishing an engaged relationship between the patient and the health provider are key enablers that orientate decision-making processes.

Moreover, the combination of the above-mentioned concepts may help health providers to better know their patients with a consequent reduction of uncertainty (a further relational ethics action which was less stressed in the reviewed articles). As difficulties of understanding specific courses of action or decision making (due to value-based demands) may arise,

patients' narrative—by involving a deeper knowledge and an effective engagement between patients and providers—may help lowering the levels of uncertainty. Finally, relational ethics action of environment matches with PCC features of patients' integration within the environment and patient as part of society. In this regard, the relationship between the patient (person) and the social context (family, friends, community, patients' history) assumes an important role in orientating treatment plans.

This work has implications for both theory, research, and practice. Regarding theoretical and research implications, this study provides a contribution to on-going academic debate on the ethical foundations of person-centered approaches to health care. As regards practical implications, by relating PCC and relational ethics approaches within health organizations—one can appreciate the differences and hence the higher ethical level contribution of PCC in not only establishing ethical provider-patient relationships but in elevating this relationship on the level of partnership and co-creation of the healthcare plan, and therefore both having active roles in clinical decision-making while fully embracing the biopsychosocial model of care. Furthermore, PCC considers patients as assets within the health system by appreciating their capabilities and resources. The most notable practical implication is if PCC is formalized into policy documents. This may be a driver for reaching higher quality standards and safer health care. From a policy-making point of view, formalizing these actions into official documents would allow a better implementation of PCC and relational

ethics within healthcare organizations' strategies. By considering patients as persons-partners, organizations are contributing to patients' empowerment and are recognizing their role as active part in care and of society.

Treating patients as persons, partners, mutual respect, embodied knowledge, and engagement—in order to enhance quality and safety of care—are the key points emerging from this research.

However, these principles are not new to medicine and have their foundations back to Aristotle and Hippocrates times (400 BCE). Hippocrates' focus was not just on the mere treatment of patients' diseases but also on the individual as a person. To this extent, his school set up a code of conduct (moral and personal code of conduct) identifying persons' needs as the pillars of care (57). In the same line, Galen's philosophy (centuries later) put the individual first as well as William Osler (between the nineteenth and twentieth century), whose focus was on the individual as a person. In this regard, Osler's contribution was fundamental for the further development of PCC philosophy. His quotation "listen to your patient, he is telling you the diagnosis" already incorporated PCC's principles of establishing a patient-provider relationship and emphasized the importance of listening and documenting patients' needs (58).

Strengths and Limitations

There are both strengths and limitations in the scoping review conducted for this paper. We identified subjectivity of reviewers as one of the main limitations of this study. This is common a weakness of qualitative analysis. Lack of language pluralism in publications selected by the research team is another limitation of this work, as only primarily publications in English language were included (articles written in any other language were excluded). Furthermore, books, book chapters and conference proceedings were excluded, and this may have further compromised the number of published items which were screened. A further limitation lies in the use of a limited set of databases (namely, Scopus, Medline, and PubMed) for our search strategy and thus some relevant papers which were not listed on the referred three databases may have been missed. However, having included both qualitative and quantitative studies, as well as mixed studies, literature reviews and commentaries—without geographical limitations—rendered strength to this review.

This scoping review took a broad approach with regard to geographical areas and did not take into consideration differences between countries when it comes to the different types of political and health systems. In this respect, the way that PCC is implemented in publicly funded health systems may be different compared to how it is applied within market-oriented systems. Thus, further research is needed to reach a higher level of understanding of PCC from an ethical perspective and its application within different health systems.

CONCLUSIONS

The aim of this scoping review is to explore whether or not person-centered care (PCC), in its quest to deliver high quality and safe health care, has a relational-ethics perspective. The

results of the review suggested that PCC dimensions are closely linked to relational ethics actions and therefore confirms Ekman et al. (7) assertion that person-centered care is an ethical philosophy of care. Indeed, due to its characteristics, PCC already incorporates relational ethics within itself. As noted earlier, PCC draws upon the contention that the patient is regarded as a person with one's own unique characteristics, background, history, strengths and limitations. The person is not only a focal point in a health system as is described in patient-centered care but as a partner and co-creator of the healthcare plan as is emphasized in PCC. In person-centered care, the patient shifts from a passive role to an active role and utilizes his/her capabilities and resources. The foundations of this approach can be retrieved back to Hippocrates time and, more recently, Osler who emphasized the importance of patient-provider relationship and listening to patients' history in order to identify most suitable treatment plans. This strong relationship between patients and health providers is required not only to agree on treatments, services and care delivery but also to incorporate and document the person's needs (health, social, psychological, work, family, society), expectations and wishes. In so doing, it is envisaged that quality of care will be higher, and costs will be better contained. All is to be based on patients' characteristics, needs, and expectations (7).

However, while reviewed articles showed that PCC features and pillars are embraced by relational ethics actions, the way that PCC is practiced seems to be lacking for some authors, and for other authors PCC seems to be closer to the relational ethics framework. Thus, PCC may not be understood or practiced in its entirety within the relational ethical framework, so much so that Rockwell (59) critiqued PCC in residential care facilities as remaining within the biomedical model and concluded and recommended to expand the focus to relational care. This means that not always PCC encompasses entirely the relational ethics components. This observation also emerged from reviewed articles, where for example the relational ethics action of uncertainty was not recurrent and the other actions.

Furthermore, PCC goes beyond the relational ethics framework in the way that features such as documentation and patients' narrative enhance the way of communication between patients and providers. In this respect, communication is not just verbal and/or visual, but it is also formalized into official documents being thus part of management plans and decision-making processes. In a PCC approach, the persons as patients have capabilities and resources that the PCC relationship should uncover to ensure provider-patient partnership and the emphasis on the patient's narrative that can be documented. PCC relationship leads to the provider-patient co-creation of the healthcare plan.

In conclusion, this paper reveals that while PCC features embrace most of the relational ethics approaches, these are not exploited in their entirety and therefore PCC emerges as a unique ethical stance in healthcare. PCC's ethical approach goes beyond what is explained within provider-patient relational ethics and emphasizes that the patient as an active person with capabilities and resources. This distinction enables us to explain

the paradigm shift from “patient-centered” to “person-centered” care. The healthcare provider partnership and co-creation of the healthcare plan contributes to the delivery of high quality, safe and cost-contained healthcare.

AUTHOR CONTRIBUTIONS

GT and SB conceived the idea, developed the methodology/search strategy, and lead the manuscript. Furthermore, they were involved in writing, editing, and

reviewing the manuscript. AR and MC contributed in the review of articles and editing of the paper. GG contributed in the first development of the idea/concept and in the final editing the manuscript.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2020.00044/full#supplementary-material>

REFERENCES

1. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for 21st Century*. Washington, DC: National Academy Press (2001).
2. Leplege A, Gzil F, Cammellin M, Lefevre C, Pachoud B, Ville I. Person-centredness: conceptual and historical perspectives. *Disabil Rehabil.* (2007) 29:1555–65. doi: 10.1080/09638280701618661
3. Olsson LE, Karlsson J, Ekman I. The integrated care pathway reduced the number of hospital days by half: a prospective comparative study of patients with acute hip fracture. *J Orthop Surg Res.* (2006) 1:3. doi: 10.1186/1749-799X-1-3
4. Edvardsson D, Winblad B, Sandman PO. Person-centred care of people with severe Alzheimer's disease: current status and ways forward. *Lancet Neurol.* (2008) 7:362–7. doi: 10.1016/S1474-4422(08)70063-2
5. Balint E. The possibilities of patient-centered medicine. *J R Coll Gen Pract.* (1969) 17:269–76.
6. Stewart MA, McWhinney IR, Buck CW. The doctor/patient relationship and its effect upon outcome. *J R Coll Gen Pract.* (1979) 29:77–82.
7. Ekman I, Swedberg K, Taft C, Lindseth A, Norberg A, Brink E, et al. Person-centered care—ready for prime time. *Euro J Cardiovasc Nurs.* (2011) 10:248–51. doi: 10.1016/j.ejcnurse.2011.06.008
8. Sen A. Capability and Well-being. In: Nussbaum M, Sen A, editors. *The Quality of Life Oxford*. Oxford: Clarendon Press (1990). p. 30–53. doi: 10.1093/0198287976.003.0003
9. Sen A. *Inequality Reexamined*. Oxford: Oxford University Press (1992).
10. Sen A. *Development as Freedom*. New York, NY: Alfred A. Knopf (1999).
11. Sen A. Why health equity? *Health Econ.* (2002) 11:659–66. doi: 10.1002/hec.762
12. Arnott N, Paliadelis P, Cruickshank M, (eds). *The Road to Nursing*. Cambridge: Cambridge University Press. (2018). doi: 10.1017/9781108393973
13. Wolf A, Vella R, Fors A. The impact of person-centred care on patients' care experiences in relation to educational level after acute coronary syndrome: secondary outcome analysis of a randomised controlled trial. *Euro J Cardiovasc Nurs.* (2019) 18:299–308. doi: 10.1177/1474515118821242
14. McCormack B, Dewing J, Breslin L, Coyne-Nevin A, Kennedy K, Manning M, et al. Developing person-centred practice: nursing outcomes arising from changes to the care environment in residential settings for older people. *Int J Older People Nurs.* (2010) 5:93–107. doi: 10.1111/j.1748-3743.2010.00216.x
15. Howie-Esquivel J, Dracup K. Communication with hospitalized heart failure patients. *Eur J Cardiovasc Nurs.* (2011) 11:216–22. doi: 10.1016/j.ejcnurse.2011.03.006
16. Ricoeur P. *Oneself as Another (Soy-même comme un autre)* 1992. Chicago, IL: University of Chicago Press Kathleen Blamey (1990).
17. Sen A. Capability and well-being. In: Nussbaum S, editor. *The quality of life*. Oxford: Clarendon Press (1993). p. 30.
18. Pollard CL. What is the right thing to do: use of a relational ethic framework to guide clinical decision-making. *Int J Caring Sci.* (2015) 8:362–8.
19. Roter D, Hall JA. *Doctors Talking With Patients/Patients Talking With Doctors: Improving Communication in Medical Visits*. Greenwood Publishing Group (2006).
20. Charon R. The patient–physician relationship. Narrative medicine: a model for empathy, reflection, profession, and trust. *JAMA.* (2001) 286:1897–902. doi: 10.1001/jama.286.15.1897
21. Engel G. The clinical application of the biopsychosocial model. *Am J Psychiatry.* (1980) 137:535–44. doi: 10.1176/ajp.137.5.535
22. Stewart MA. Effective physician-patient communication and health outcomes: a review. *CMAJ.* (1995) 152:1423.
23. Stewart M. Towards a global definition of patient centred care: the patient should be the judge of patient centred care. *BMJ.* (2001) 322:444–5. doi: 10.1136/bmj.322.7284.444
24. Stewart MA. What is a successful doctor-patient interview? A study of interactions and outcomes. *Soc Sci Med.* (1984) 19:167–75. doi: 10.1016/0277-9536(84)90284-3
25. Levenstein JH, McCracken EC, McWhinney IR, Stewart MA, Brown JB. The patient-centred clinical method. I A model for the doctor-patient interaction in family medicine. *Family Pract.* (1986) 3:24–30. doi: 10.1093/famp/3.1.24
26. Griffin SJ, Kinmonth AL, Veltman MW, Gillard S, Grant J, Stewart M. Effect on health-related outcomes of interventions to alter the interaction between patients and practitioners: a systematic review of trials. *Ann Family Med.* (2004) 2:595–608. doi: 10.1370/afm.142
27. Borrell-Carrió F, Suchman AL, Epstein RM. The biopsychosocial model 25 years later: principles, practice, and scientific inquiry. *Ann Family Med.* (2004) 2:576–82. doi: 10.1370/afm.245
28. Hosmer LT. Trust: The connecting link between organizational theory and philosophical ethics. *Acad Manage Rev.* (1995) 20:379–403. doi: 10.2307/258851
29. Bergum V, Dossetor JB. Relational Ethics: *The Full Meaning of Respect*. Hagerstown, MD: University Publishing Group (2005). p. 165–96.
30. Evans DT. Behind the headlines: sexual health implications for nursing ethics and practice. *Prim Health Care.* (2004) 14:40–50. doi: 10.7748/phc2004.10.14.8.40.c525
31. Austin W, Bergum V, Goldberg L. Unable to answer the call of our patients: mental health nurses' experience of moral distress. *Nurs Inq.* (2003) 10:177–83. doi: 10.1046/j.1440-1800.2003.00181.x
32. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Ann Intern Med.* (2018) 169:467–73. doi: 10.7326/M18-0850
33. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med.* (2009) 151:264–9. doi: 10.7326/0003-4819-151-4-200908180-00135
34. Abbott KM, Heid AR, van Haitsma K. We Can't provide season tickets to the opera: Staff perceptions of providing preference-based, person-centered care. *Clin Gerontol.* (2016) 39:190–209. doi: 10.1080/07317115.2016.1151968
35. Boscart VM, Davey M, Ploeg J, Heckman G, Dupuis S, Sheiban L, et al. Psychometric evaluation of the team member perspectives of person-centered care (TM-PCC) survey for long-term care homes. *Healthcare.* (2018) 6:E59. doi: 10.3390/healthcare6020059
36. Coyne I, Holmström I, Söderbäck M. Centeredness in healthcare: a concept synthesis of family-centered care, person-centered care and child-centered care. *J Pediatr Nurs.* (2018) 42:45–56. doi: 10.1016/j.pedn.2018.07.001
37. Edvardsson D, Fetherstonhaugh D, Nay R. Promoting a continuation of self and normality: person-centred care as described by people with dementia, their family members and aged care staff. *J Clin Nurs.* (2010) 19:2611–8. doi: 10.1111/j.1365-2702.2009.03143.x
38. Edvardsson D, Sandman PO, Borell L. Implementing national guidelines for person-centered care of people with dementia in residential aged

- care: Effects on perceived person-centeredness, staff strain, and stress of conscience. *Int Psychogeriatr.* (2014) 26:1171–9. doi: 10.1017/S1041610214000258
39. Elfström T, Kajonius PJ, Kazemi A. The impact of personality on person-centred care: a study of care staff in Swedish nursing homes. *Int J Older People Nurs.* (2017) 12:12132. doi: 10.1111/opn.12132
 40. Hung L, Chaudhury H, Rust T. The effect of dining room physical environmental renovations on person-centered care practice and residents' dining experiences in long-term care facilities. *J Appl Gerontol.* (2016) 35:1279–301. doi: 10.1177/0733464815574094
 41. Alharbi TSJ, Ekman I, Olsson L, Dudas K, Carlström E. Organizational culture and the implementation of person centered care: results from a change process in Swedish hospital care. *Health Policy.* (2012) 108:294–301. doi: 10.1016/j.healthpol.2012.09.003
 42. Dudas K, Olsson L, Wolf A, Swedberg K, Taft C, Schaufelberger M, et al. (2013). Uncertainty in illness among patients with chronic heart failure is less in person-centred care than in usual care. *Euro J Cardiovasc Nurs.* (2012) 12:521–8. doi: 10.1177/1474515112472270
 43. Fawcett TN, Rhynas SJ. Re-finding the 'human side' of human factors in nursing: Helping student nurses to combine person-centred care with the rigours of patient safety. *Nurse Educ Today.* (2014) 34:1238–41. doi: 10.1016/j.nedt.2014.01.008
 44. Howard EP, Schreiber R, Morris JN, Russotto A, Flashner-Fineman S. COLLAGE 360: a model of person-centered care to promote health among older adults. *J Ageing Res Healthcare.* (2016) 1:21–30. doi: 10.14302/issn.2474-7785.jarh-16-1123
 45. Johnston B, Pringle J, Gaffney M, Narayanasamy M, McGuire M, Buchanan D. The dignified approach to care: a pilot study using the patient dignity question as an intervention to enhance dignity and person-centred care for people with palliative care needs in the acute hospital setting psychosocial. *BMC Palliative Care.* (2015) 14:9. doi: 10.1186/s12904-015-0013-3
 46. Kulski K, Peckham A, Williams AP, Upshur RE. What gets in the way of person-centred care for people with multimorbidity? Lessons from Ontario, Canada. *Healthcare Quart.* (2016) 19:17–23. doi: 10.12927/hcq.2016.24694
 47. Sjögren K, Lindkvist M, Sandman P, Zingmark K, Edvardsson D. Organisational and environmental characteristics of residential aged care units providing highly person-centred care: a cross sectional study. *BMC Nurs.* (2017) 16:44. doi: 10.1186/s12912-017-0240-4
 48. Stanhope V, Tondora J, Davidson L, Choy-Brown M, Marcus SC. Person-centered care planning and service engagement: a study protocol for a randomized controlled trial. *Trials.* (2015) 16:180. doi: 10.1186/s13063-015-0715-0
 49. McCormack B, Dewing J, McCance T. Developing person-centred care: addressing contextual challenges through practice development. *Online J Issues Nurs.* (2011) 16:3.
 50. Mills I, Frost J, Kay E, Moles DR. Person-centred care in dentistry - the patients' perspective. *Br Dent J.* (2015) 218:407–13. doi: 10.1038/sj.bdj.2015.248
 51. Geboy L. Linking person-centered care and the physical environment: 10 Design principles for elder and dementia care staff. *Alzheimer's Care Today.* (2009) 10:228–31. doi: 10.1097/ACQ.0b013e3181bef153
 52. Røsvik J, Kirkevold M, Engedal K, Brooker D, and Kirkevold O. A model for using the VIPS framework for person-centred care for persons with dementia in nursing homes: A qualitative evaluative study. *Int J Older People Nurs.* (2011) 6:227–36. doi: 10.1111/j.1748-3743.2011.00290.x
 53. Røen I, Kirkevold Ø, Testad I, Selbæk G, Engedal K, Bergh S. Person-centered care in norwegian nursing homes and its relation to organizational factors and staff characteristics: a cross-sectional survey. *Int Psychogeriatr.* (2018) 30:1279–90. doi: 10.1017/S1041610217002708
 54. Rubashkin N, Warnock R, Diamond-Smith N. A systematic review of person-centered care interventions to improve quality of facility-based delivery. *Reprod Health.* (2018) 15:169. doi: 10.1186/s12978-018-0588-2
 55. Scales K, Bailey S, Middleton J, Schneider J. Power, empowerment, and person-centred care: Using ethnography to examine the everyday practice of unregistered dementia care staff. *Sociol Health Illness.* (2017) 39:227–43. doi: 10.1111/1467-9566.12524
 56. English J. Training doctors for person-centered care. *Acad Med.* (2016) 91:294–6. doi: 10.1097/ACM.0000000000001073
 57. Srinivasan M. From the editors' desk: Hippocrates and patient-centered medicine. *J Gen Intern Med.* (2012) 27:135. doi: 10.1007/s11606-011-1948-6
 58. Waeber G. Just listen to your patient, he is telling you the diagnosis. *Forum Méd Suisse.* (2019) 19:373. doi: 10.4414/fms.2019.08098
 59. Rockwell J. From person-centered to relational care: expanding the focus in residential care facilities. *J Gerontol Soc Work.* (2012) 55:233–48. doi: 10.1080/01634372.2011.639438

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