The Health Benefits of ISO Standards: Contemporary Research

International Organization for Standardization

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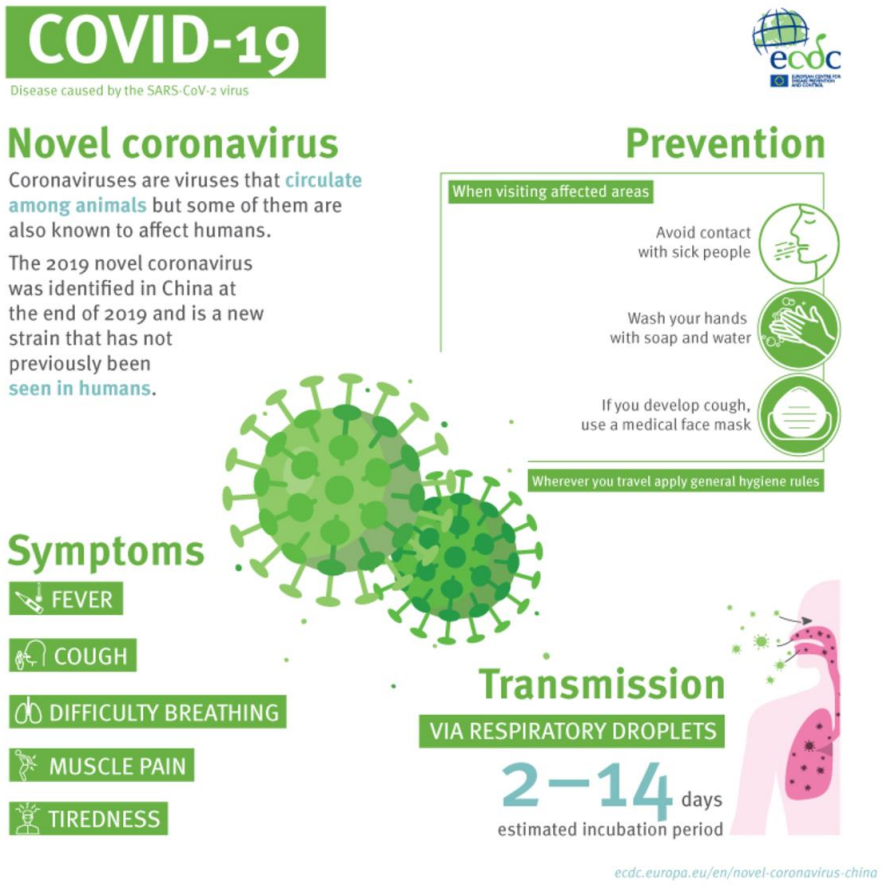


The pandemic brought a significant number of wide-ranging challenges across the world.

Importance of the United Nations 17 Sustainable Development Goals (SDGs) which, through their targets, have the power to affect most aspects of people's lives.

A Foundation of Standards

BS ISO/IEC 15504
The concepts of process assessment and its use in process improvement and process capability determination

ISO/IEC TS 17021-4:2013
Conformity assessment - Requirements for bodies providing audit and certification of management systems

ISO 19011:2011
Guidelines for auditing management systems.

ISO/IEC 17065
Conformity assessment — Requirements for bodies certifying products, processes, and services.

ISO 10006:2006
Quality management systems - Guidelines for quality management in projects

ISO 14000 Series
14001: Environmental Management Systems
14004: EMS General Guidelines
14010: Guidelines for Auditing of an EMS14012: Auditing - Qualification Criteria

ISO 20121:2012
specifies requirements for an event sustainability management system for any type of event or event-related activity and provides guidance on conforming to those requirements

ISO 21500:2012
Guidance on Project Management

ISO 9000 Series
ISO 9001:2008 - sets out the requirements of a quality management system

ISO 9000:2005 - covers the basic concepts and language

ISO 9004:2009 - focuses on how to make a quality management system more efficient and effective

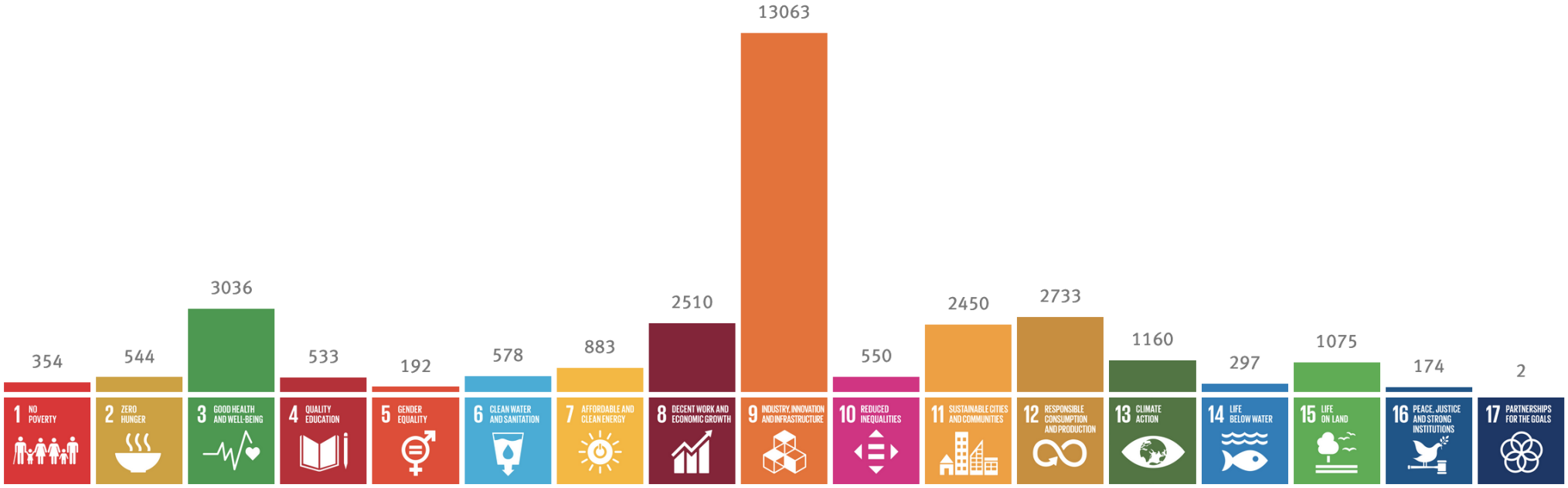
ISO 19011:2011 - sets out guidance on internal and external audits of quality management systems.

International standards represent a powerful instrument to influence the development of services, policies, products, and environments. They help society in a post-pandemic scenario to accelerate the achievement of the SDGs.

There are currently 17 SDGs and more than 20,000 international standards across the world addressing topics such as manufactured products, technology, food safety, agriculture, and healthcare.

IMPACT AT A GLANCE

ISO contributes to all of the SDGs. Here you can see the number of ISO standards that are directly applicable to each Goal.



Research questions

How can we improve knowledge of the use of ISO standards and promote their benefits by purposefully connecting them with SDGs?

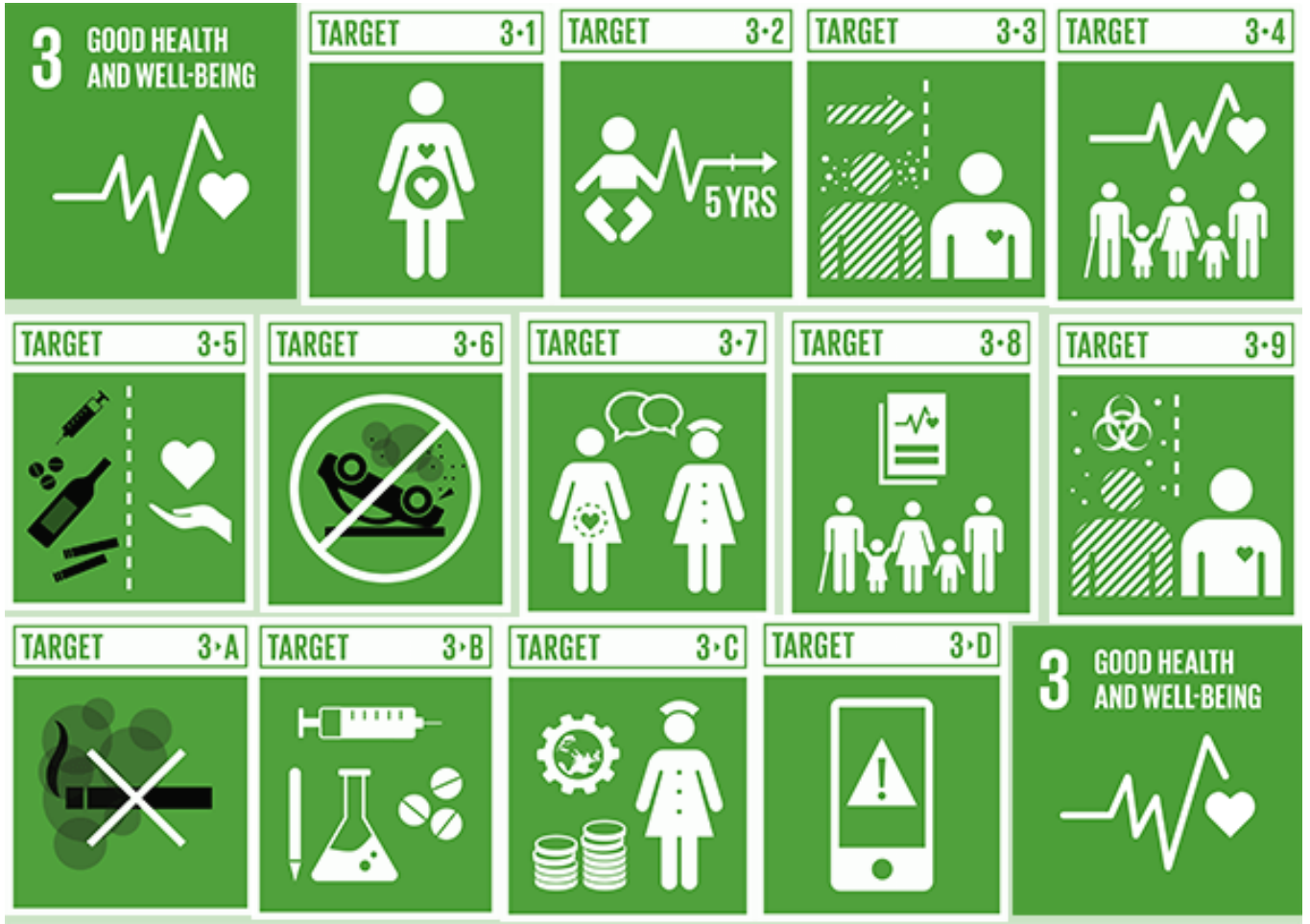
What evidence-based method could help to verify the connection between ISO standards and SDGs to allow for an improved impact of the standards among stakeholders, by offering insights to achieve the SDGs targets?

Project Overview

The Centre for eIntegrated Care (CeIC), through a dedicated research team (engaged with ISO committees at national and international level), is contracted by ISO (International Organization for Standardization) to conduct a mixed-method study with the overarching goals of developing a knowledge infographic framework, fostering a connection with international standards experts, and highlighting the impact and benefits that ISO standards have on SDG 3.

This process would allow us to build upon existing knowledge generated by ISO and other expert communities and verify, with evidence, the connections between international standards and SDGs focusing on practice-led strategies.

SDG N°3: Ensure healthy lives and promote well-being for all at all ages



Our Team

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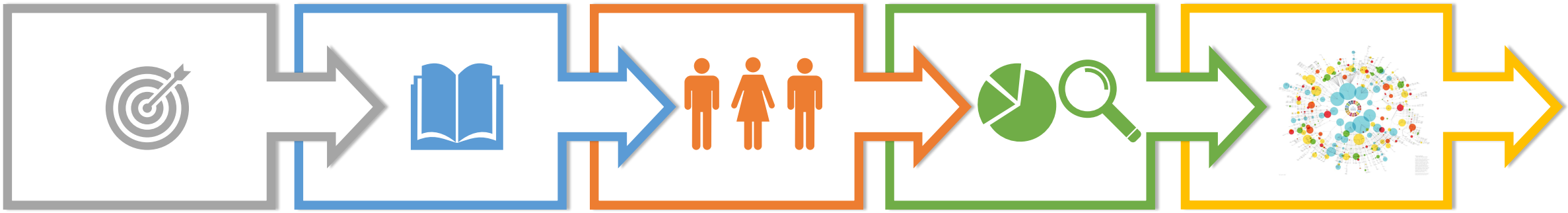
Research methodology



SDG Domain Selection

Quantitative Study: State of the Art

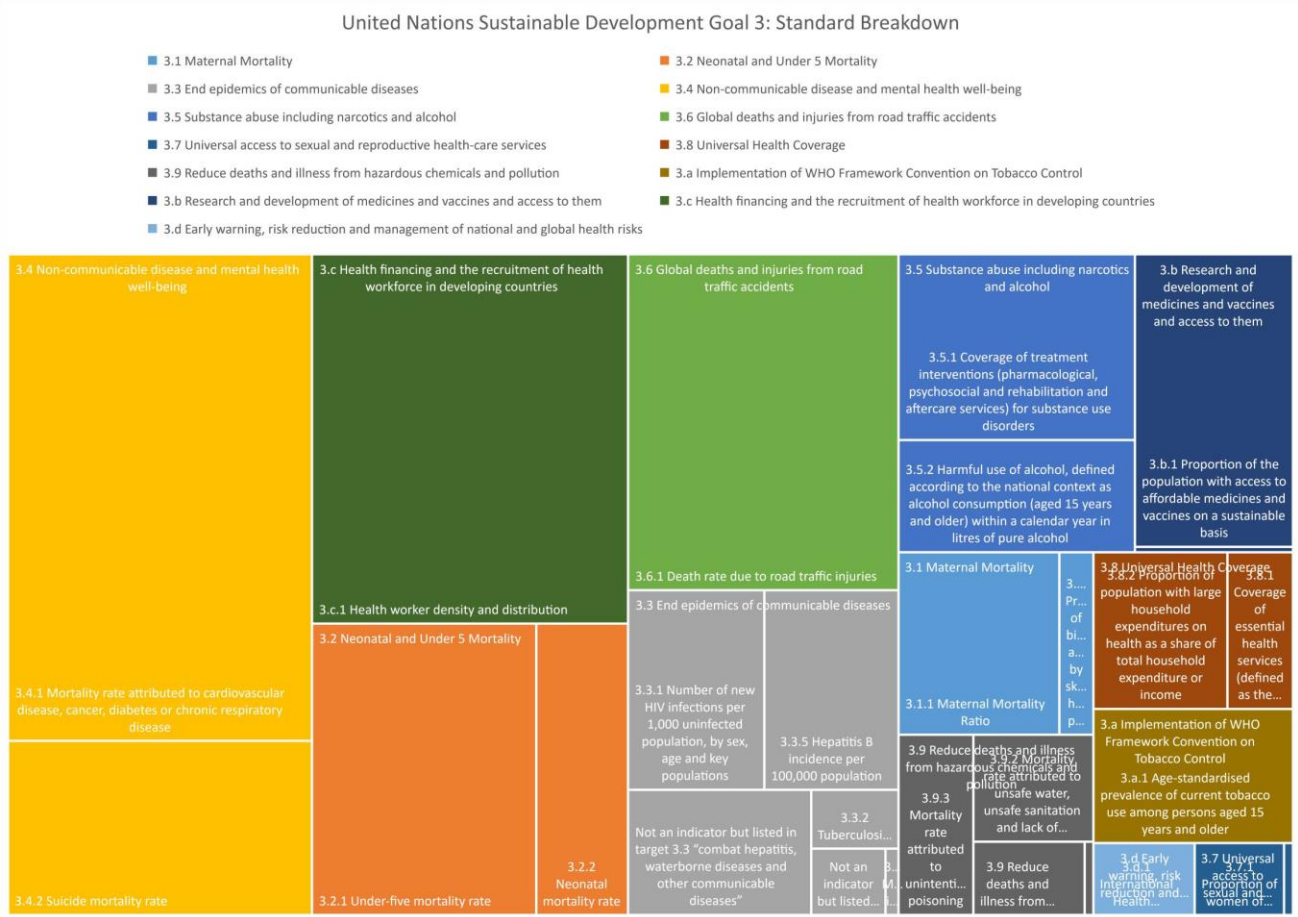
Partnering & Qualitative Study

Data Analysis & Validation

Infographic Framework Implementation

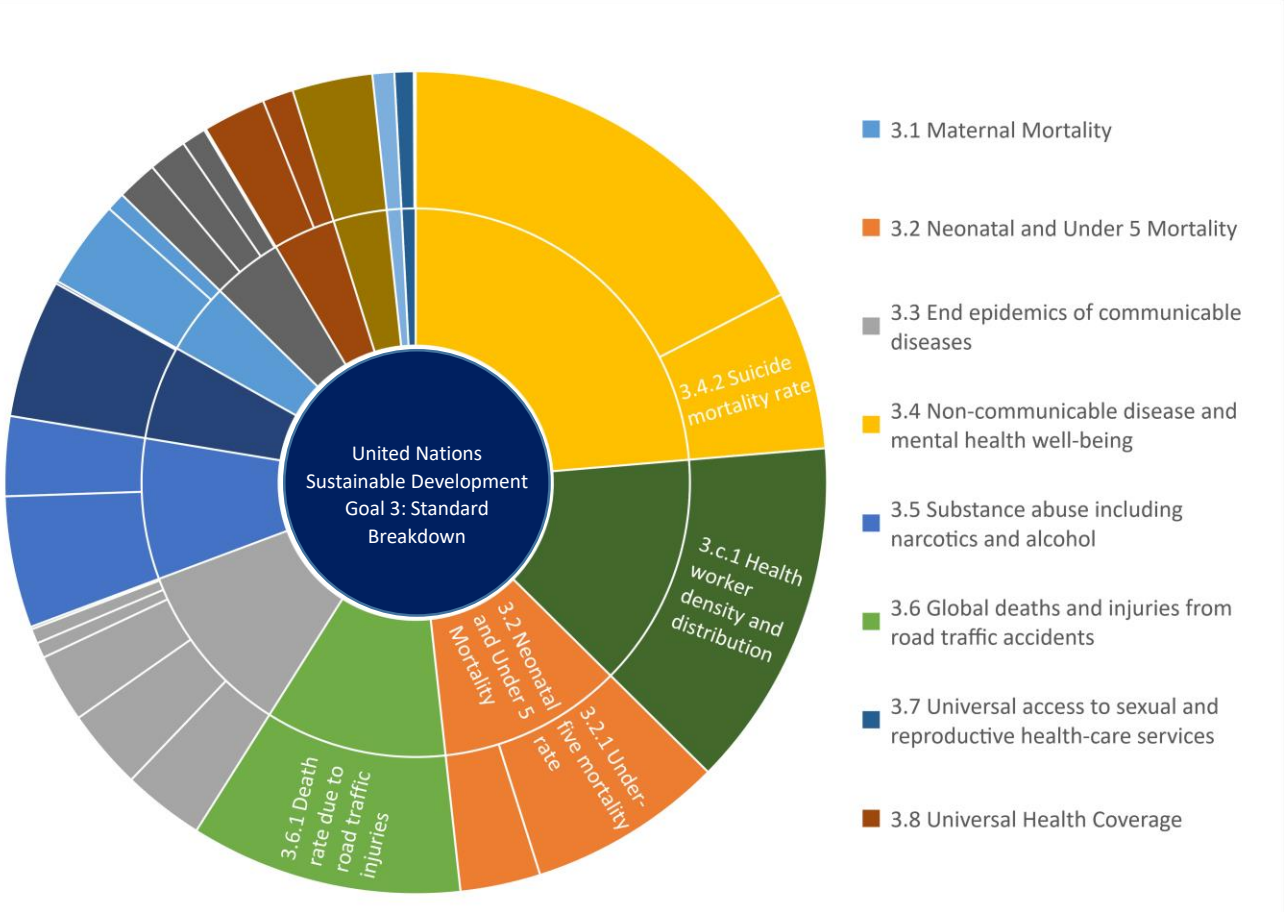
Research goal

To build upon existing knowledge generated by ISO and other expert communities, and verify, with evidence, the connections between international standards and SDGs focusing on practice-led strategies.



Quantitative Study

- Keywords related to SDG3 targets were identified
- Search conducted using ISO Online Browsing Platform
- In total, 28,624 standards were found to contain one of the keywords searched
- 3,964 standards relating to “Health, medicine, and laboratory equipment” were found

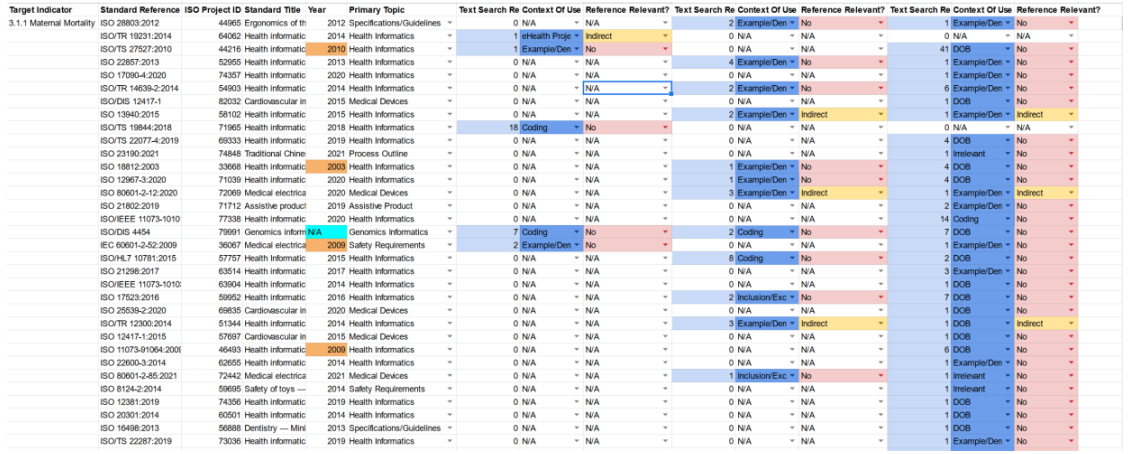


Determining Impact/Relevance through Text Analysis approaches

- Two independently developed approaches for determining relevance of a standard
- NVIVO was used for a pilot analysis of 100 standards
- R was used for a pilot analysis of 30 standards

NVIVO Document Analysis Software

- Document analysis software that facilitates text-mining functionality
- 100 standards were imported to NVIVO
- Exploration function was use to conduct text searches of keywords
- E.g: ‘pregnancy OR pregnant OR pregna*’ returned 28 standards that contained one of the keywords outlined in the search equalling to 158 total references
- Relevance was determined by reviewing the context that the keywords were used in the standard, and reviewing the foreword/scope/introduction of the standard



Target Indicator	Standard Reference	ISO Project ID	Standard Title	Year	Primary Topic	Text Search Re	Context Of Use	Reference Relevant?	Text Search Re	Context Of Use	Reference Relevant?	Text Search Re	Context Of Use	Reference Relevant?
3.1.1 Maternal Mortality	ISO 28803:2012	44965	Ergonomics of th	2012	Specifications/Guidelines	0	N/A	N/A	2	Example/Den	No	1	Example/Den	No
	ISO/TR 19231:2014	64062	Health informatic	2014	Health Informatics	1	eHealth Proje	Indirect	0	N/A	N/A	0	N/A	N/A
	ISO/TS 27527:2010	44216	Health informatic	2010	Health Informatics	1	Example/Den	No	0	N/A	N/A	41	DOB	No
	ISO 22857:2013	52955	Health informatic	2013	Health Informatics	0	N/A	N/A	4	Example/Den	No	1	Example/Den	No
	ISO 17090-4:2020	74357	Health informatic	2020	Health Informatics	0	N/A	N/A	0	N/A	N/A	1	Example/Den	No
	ISO/TR 14639-2:2014	54903	Health informatic	2014	Health Informatics	0	N/A	N/A	2	Example/Den	No	6	Example/Den	No
	ISO/DIS 12417-1	82032	Cardiovascular in	2015	Medical Devices	0	N/A	N/A	0	N/A	N/A	1	DOB	No
	ISO 13940:2015	58102	Health informatic	2015	Health Informatics	0	N/A	N/A	2	Example/Den	Indirect	1	Example/Den	Indirect
	ISO/TS 19844:2018	71965	Health informatic	2018	Health Informatics	18	Coding	No	0	N/A	N/A	0	N/A	N/A
	ISO/TS 22077-4:2019	69333	Health informatic	2019	Health Informatics	0	N/A	N/A	0	N/A	N/A	4	DOB	No
	ISO 23190:2021	74848	Traditional Chine	2021	Process Outline	0	N/A	N/A	0	N/A	N/A	1	Irrelevant	No
	ISO 18812:2003	33668	Health informatic	2003	Health Informatics	0	N/A	N/A	1	Example/Den	No	4	DOB	No
	ISO 12967-3:2020	71039	Health informatic	2020	Health Informatics	0	N/A	N/A	1	Example/Den	No	4	DOB	No
	ISO 80601-2-12:2020	72069	Medical electrica	2020	Medical Devices	0	N/A	N/A	3	Example/Den	Indirect	1	Example/Den	Indirect
	ISO 21802:2019	71712	Assistive product	2019	Assistive Product	0	N/A	N/A	0	N/A	N/A	2	Example/Den	No
	ISO/IEEE 11073-1010	77338	Health informatic	2020	Health Informatics	0	N/A	N/A	0	N/A	N/A	14	Coding	No
	ISO/DIS 4454	79991	Genomics inform	N/A	Genomics Informatics	7	Coding	No	2	Coding	No	7	DOB	No
	IEC 60601-2-52:2009	36067	Medical electrica	2009	Safety Requirements	2	Example/Den	No	0	N/A	N/A	1	Example/Den	No
	ISO/HL7 10781:2015	57757	Health informatic	2015	Health Informatics	0	N/A	N/A	8	Coding	No	2	DOB	No
	ISO 21298:2017	63514	Health informatic	2017	Health Informatics	0	N/A	N/A	0	N/A	N/A	3	Example/Den	No
	ISO/IEEE 11073-1010	63904	Health informatic	2014	Health Informatics	0	N/A	N/A	0	N/A	N/A	1	DOB	No
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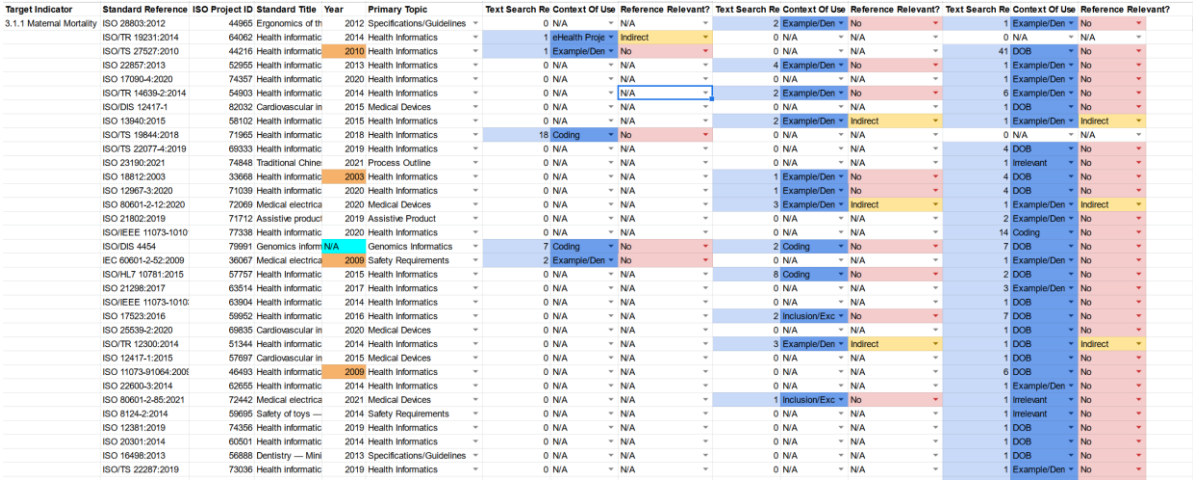
	ISO/TR 12300:2014	51344	Health informatic	2014	Health Informatics	0	N/A	N/A	3	Example/Den	Indirect	1	DOB	Indirect
	ISO 12417-1:2015	57697	Cardiovascular in	2015	Medical Devices	0	N/A	N/A	0	N/A	N/A	1	DOB	No
	ISO 11073-91064:200	46493	Health informatic	2009	Health Informatics	0	N/A	N/A	0	N/A	N/A	6	DOB	No
	ISO 22600-3:2014	62655	Health informatic	2014	Health Informatics	0	N/A	N/A	0	N/A	N/A	1	Example/Den	No
	ISO 80601-2-85:2021	72442	Medical electrica	2021	Medical Devices	0	N/A	N/A	1	Inclusion/Exc	No	1	Irrelevant	No
	ISO 8124-2:2014	59695	Safety of toys —	2014	Safety Requirements	0	N/A	N/A	0	N/A	N/A	1	Irrelevant	No
	ISO 12381:2019	74356	Health informatic	2019	Health Informatics	0	N/A	N/A	0	N/A	N/A	1	DOB	No
	ISO 20301:2014	60501	Health informatic	2014	Health Informatics	0	N/A	N/A	0	N/A	N/A	1	DOB	No
	ISO 16498:2013	56888	Dentistry — Mini	2013	Specifications/Guidelines	0	N/A	N/A	0	N/A	N/A	1	DOB	No
	ISO/TS 22287:2019	73036	Health informatic	2019	Health Informatics	0	N/A	N/A	0	N/A	N/A	1	Example/Den	No

Scalable Text Analysis Overview Document

- Information gathered from text analysis was used to populate an Google spreadsheet (can be done through Excel as well) which provides an overview of a standard's information and relevance.
- Heading columns can be scaled up or down depending on the number of 'key words' searched using text analysis software
- Automatically changes colour based on information input to a cell (e.g. relevant = green, indirectly relevant = yellow, not relevant = red.



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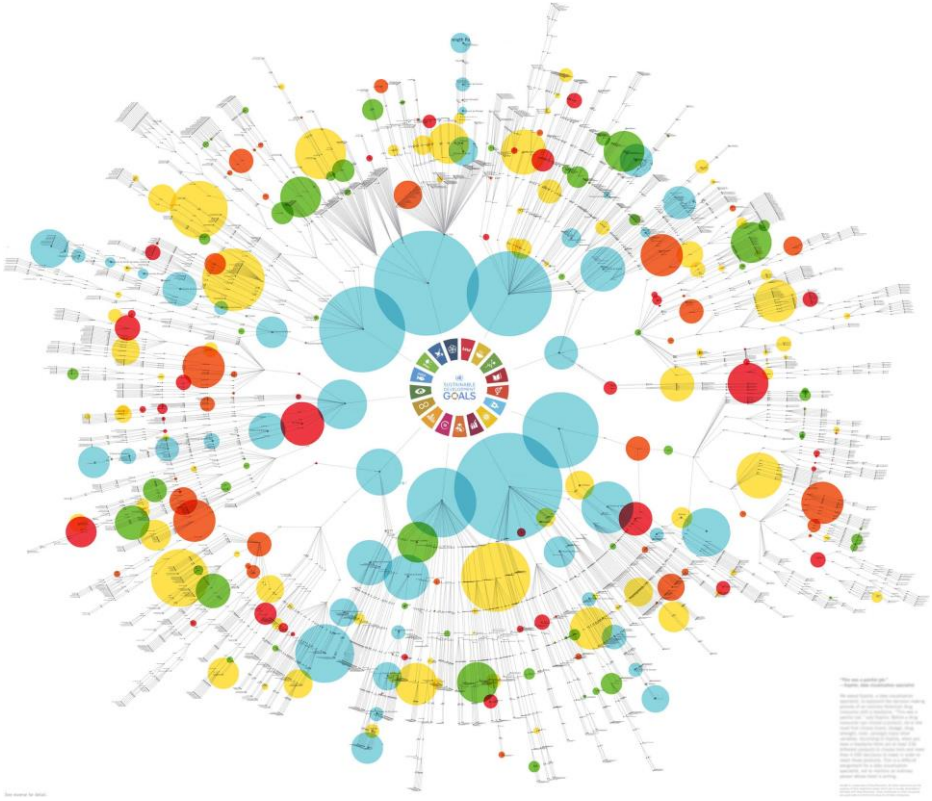
R Statistical Computing Software

- Powerful software that can be programmed to analyse documents input into it
- 30 standards were inputted into R
- ‘Keywords’ were searched with a correlation limit of 0.75 to identify other terms not initially identified
- Outputs a breakdown that shows the keywords, and correlated terms and their occurrence in the inputted documents.
- Relevance can be determined through keyword occurrence in the document

```
> inspect(opinions.tdm[c("pregnancy", "fertility", "women", "ectopic", "pregnant"),])
<<TermDocumentMatrix (terms: 5, documents: 30)>>
Non-/sparse entries: 19/131
Sparsity           : 87%
Maximal term length: 9
Weighting          : term frequency (tf)
Sample             :
           Docs
Terms       iso_10993.pdf iso_11073.pdf iso_11249.pdf iso_12417-ed2.pdf iso_12417.pdf iso_12967-3.pdf iso_13022.pdf
  ectopic               0             2             5                 0             0             0             1
  fertility             0             0             2                 1             1             0             0
  pregnancy             0             0            59                 0             0             1             1
  pregnant              0             0             3                 0             0             0             0
  women                 2             0            24                 0             0             0             0
           Docs
Terms       iso_13606-1.pdf iso_13940.pdf iso_4454.pdf
  ectopic                 0             0           0
  fertility               0             0           0
  pregnancy               3             1           2
  pregnant                0             1           0
  women                   0             0           1
```

Outcome

Evidence-based validation of the theoretical foundations identified by the ISO committee and other relevant sources and a thorough ISO-SDG graph database including a mapping to relevant standards to allow for knowledge democratization of the links between standards and SDGs, how they are used and in what context adopted.



Thank you for your attention

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