Da JMRS - Journal of Medical Radiation Sciencies: la valutazione dell'impatto del Sistema di Qualità dello Screening Mammografico in Regione Emilia-Romagna
Lauro Bucchi

L'articolo

An image quality review programme in a population-based mammography screening service

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Perché pubblicare il protocollo (e sommari risultati) del 'Sistema' della Regione Emilia-Romagna?

- per sottoporlo a un giudizio esperto terzo e indipendente

- per offrire una garanzia ai TSRM che vi partecipano e alle altre Regioni che lo hanno adottato volontariamente

- per comunicarne i metodi ad altri

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An image quality review programme in a population-based mammography screening service

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On an international scale, the variety of approaches proposed for IQ assessment in the area of mammography screening suggests that a widely accepted method to monitor and optimise the performance of radiographers has not been developed yet.[1,17] It remains necessary to disseminate and evaluate the methods and the results of all ongoing experiences. The programme described here is not designed to set up a central control system. It places the emphasis on motivating and training the radiographers and not on testing them or ranking them or certifying their competence. This strategy made it possible to face a rapid growth of over 125% in mammogram volume – a sort of natural experiment – with only a transient decrease in IQ.

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exposure time for each mammogram and assist the radiologist in special procedures. In this article, we report on an Italian regional radiographer-oriented mammographic IQ review programme. We illustrate the ideas and concepts that underlie the programme, the objectives, the design, the actors and their roles, the implementation and the results.

Materials and Methods

Setting and background

In the Emilia-Romagna Region (northern Italy), a two-yearly, two-view, double-read mammography screening service for women aged 50–69 years was established in the second half of the 1990s.[6] According to data of 2018, the programme is served by 47 imaging facilities and 79 digital mammography systems, including 68 direct radiography systems and 11 computed radiography systems. The transition to digital mammography was completed in 2010–2011. There are 107 dedicated and 89 non-dedicated radiographers, for a total 196. In Italy, both male and female radiographers are employed.

Between 1998 and 2009, the regional steering committee for screening mammography, that is composed of radiologists, radiographers, medical physicists and epidemiologists, undertook several onsite audit visits to the imaging facilities in order to review their technical characteristics. IQ, breast dosimetry and mammography sensitivity, with evaluation of incidence and radiologic review of interval breast cancers[7], were particularly addressed. In 2009, the target age range of the screening service was extended to 45–74 years.[8] The increase in mammography examinations was projected to be over 100%. However, no substantial adjustment of the radiographer workforce was expected. In anticipation of likely adverse effects on mammographic IQ, the audit approach was abandoned in favour of an active IQ review programme.

In its present form and in its entirety, the programme has been introduced in late 2016. Between 2010 and 2015, it has been preceded by schemes that had increasing similarities to the current model.

Rationale

The programme conforms to the 2006 European guidelines for quality assurance in breast cancer screening and diagnosis.[9] According to these, three radiographer's characteristics influence IQ, namely: training, experience and – important to note – motivation.[9] In fact, there are neither recognised nor obvious ways to increase a radiographer's motivation. Whether this key guideline is implemented or not across Europe is virtually unknown. Building radiographers' motivation is one of the expected effects of this programme.

In brief, the protocol consists of a process of mammography review and IQ classification followed by a training effort and a monitoring work. The programme has a four-stage design (Fig. 1):

1. Twice a year, each first-level radiographer, that is, a radiographer who processes the routine screening workload, reviews a set of digital mammograms performed by him/herself. This enables him/her to critically reflect on his/her own performance and to find increased motivation;
2. Individual training needs are identified by a more experienced local reference radiographer with a review of the same mammograms and an evaluation of the discrepancies;
3. Retraining activities are planned and carried out; and
4. The impact of these efforts is monitored.
   The ideas linking these stages are that:

   - Training is more effective if tailored to the educational needs of a motivated radiographer[9] and
   - This assumption should be confirmed, because monitoring the effects of training allows to identify additional educational needs.

The programme has not administrative functions. It is not designed to set up a monitoring system for central control purposes, to rank the radiographers, to certify their competence and to collect single screening centre's data for accreditation purposes.

Actors and roles

The actors of the programme are connected in a pyramidal structure, which facilitates a fluid communication and ensures the standardisation of procedures. The actors include the following:

- *The programme head*, who develops the methods and acts as a scientific guarantor;
- *The programme coordinator*, who is responsible for coordinating the agenda;
- *The programme monitor*, who receives the IQ assessment forms from the local reference radiographers and generates standard statistics;
- *The local reference radiographers* (two per screening unit), who occupy an intermediate position between the apical level and first-level radiographers;
- *The radiographers' working group*, which is composed by all of the above actors, and meets twice a year to discuss the results and plan the educational interventions; and
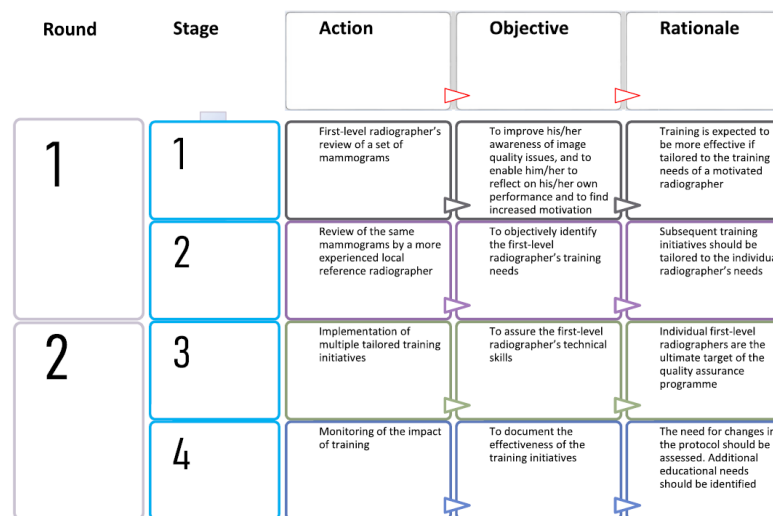
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Round	Stage	Action	Objective	Rationale
1	1	First-level radiographer's review of a set of mammograms	To improve his/her awareness of image quality issues, and to enable him/her to reflect on his/her own performance and to find increased motivation	Training is expected to be more effective if tailored to the training needs of a motivated radiographer
	2	Review of the same mammograms by a more experienced local reference radiographer	To objectively identify the first-level radiographer's training needs	Subsequent training initiatives should be tailored to the individual radiographer's needs
2	3	Implementation of multiple tailored training initiatives	To assure the first-level radiographer's technical skills	Individual first-level radiographers are the ultimate target of the quality assurance programme
	4	Monitoring of the impact of training	To document the effectiveness of the training initiatives	The need for changes in the protocol should be assessed. Additional educational needs should be identified

Figure 1. Technical scheme depicting the four-stage design of the Emilia-Romagna Region mammographic image quality review programme.

- *The first-level radiographers,* who select the samples of mammograms, perform part of the review work and participate in training activities.

Baseline training

The first implementation of the programme is preceded by a set of initiatives aimed at providing all radiographers with basic training and instructions. Events included are as follows: a preparatory region-wide meeting, targeted to the directors of the screening units and all radiographers; a centralised theoretical course of four to eight hours, targeted to local reference radiographers; and local practical courses in which groups of three first-level radiographers at once are trained to the use of the IQ assessment form.

First round

The programme has an annual duration, is repeated each year and is divided in two rounds. In the first round, each first-level radiographer in each imaging facility selects by him/herself a systematic sample of five bilateral two-view mammography examinations, for a total of 20 digital mammograms, which must have been performed consecutively in the middle of an arbitrarily selected working day with average-high workload, and must have been obtained in the standard craniocaudal and mediolateral oblique views. Among these mammograms, those from patients with pacemaker, breast implants, breast scars and large breasts requiring multiple views are excluded and replaced with the next closest mammogram.

The evaluation of mammographic IQ is subjective and prone to variations in the individual perception of observers.[10] To overcome this problem, standard assessment tools have been developed.[11–13] With these instruments, the review of images takes place against a set of well-established and widely accepted criteria. The IQ criteria used in this programme for reviewing the mammograms are listed in Table 1.

A facsimile copy of the IQ assessment form, filled and translated in English, is shown in Figure 2. The middle section should provide the radiographer's evaluation of the mammographic IQ criteria, whose simplified names are written vertically, for both views of the breast and

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Table 1. Image quality criteria used for reviewing the mammograms in the Emilia-Romagna Region mammographic image quality review programme, with the view(s) of the breast to which they apply and the weight that is specifically assigned to each technical error (criterion not met) to reflect its importance for the accuracy of the diagnostic process.

Code*	Relevant view of the breast	Image quality criterion†	Weight
A	CC, MLO	Nipple in profile	1.00
B	CC	Inframammary fold well demonstrated in internal quadrants and/or retromammary spaces	0.50
B1	CC	Inframammary fold well demonstrated in external quadrants and/or retromammary spaces	0.50
C	CC, MLO	Symmetrical images	0.10
D	CC, MLO	Absence of overlying artefacts (skin folds altering/obscuring the breast tissue, shoulder, nose, etc.)	0.50
D1	CC, MLO	Absence of small artefacts	0.10
E	CC, MLO	Breast compression ≥5 decaNewtions‡	0.25
F	CC	Absence of internal/external glandular rotation	0.25
F	MLO	Absence of upper/lower glandular rotation	0.25
G	MLO	Pectoral muscle shadow to the nipple level, full width of the pectoral muscle	1.00
H	MLO	Complete visibility of the submammary sulcus	0.75
H1	MLO	Partial visibility of the submammary sulcus profile	0.25

CC, craniocaudal; MLO, mediolateral oblique.
*Criterion identification code being indicated for clarity in all materials of the programme.
†For each criterion, the definition of the technical standard is based on the 2006 European guidelines for quality assurance in breast cancer screening and diagnosis.[14]
‡The decaNewton is a unit of force in the SI equal to 10 newtons. The amount of breast compression is automatically recorded on the mammogram or can be retrieved from the archiving and communications system (PACS) server at the imaging facility.

both breasts. The number 0 indicates that the criterion has been met, 1 indicates that it has not been met. All numbers 1 are multiplied by a weight (Table 1) varying from 0.10 to 1.00, which reflects its importance for the accuracy of the diagnostic process. The column headed 'Score' shows the sum of weighted numbers. The column headed 'Image quality category' shows the categorisation of the sum of weighted numbers, that is, the final classification of IQ (perfect indicates a sum of 0.00–0.10; excellent indicates 0.20–1.05; good indicates 1.10–2.50,

moderate indicates 2.55–3.95, poor indicates 4.00–4.95 and inadequate with need for repeat examination indicates ≥5.00). The validity of this tool relies on its close similarity with validated instruments that are in use in other countries.[11–13]

Each set of 20 mammograms undergoes two independent reviews: one performed by the radiographer him/herself and the other by one of the two local reference radiographers. Two separate IQ assessment forms are used. The initial self-review serves, in the first place, radiographer-oriented purposes: to foster his/her professional growth; to improve his/her awareness of the technical determinants of IQ; and to provide him/her with an opportunity to critically reflect on his/her performance at regular intervals.

The forms are compared by the local reference radiographer. In the case of discordant interpretations, the mammograms are reviewed by the programme head. The results of reviews have two distinct uses: determining the level of technical performance of the first-level radiographer and identifying his/her errors in interpreting the level of IQ.

The two forms are loaded in Excel files and sent to the programme monitor, who applies the appropriate weights, calculates the total IQ score of each mammogram and classifies the overall IQ into five categories (Fig. 2). This approach is derived from the IQ grading system proposed by the UK Mammography Trainers Group.[15]

The programme monitor generates standard statistics. The data are analysed descriptively. The main outcome measure in data analysis is the overall regional per cent distribution by IQ classification obtained in the round. This is directly compared with a standard distribution derived from the radiographic quality objectives put forth by the 2006 European guidelines for quality assurance in breast cancer screening and diagnosis.[9] The standard distribution is as follows:

- Inadequate, repeat needed, <1%;
- Poor + inadequate, repeat needed, <3%;
- Moderate, <12%;
- Perfect + excellent + good, >85%;
- Perfect + excellent + good + moderate, >97%.

The results are discussed in the first annual meeting of the radiographers' working group in order to plan the appropriate educational interventions.

Second round

In each screening centre, the educational interventions include the following: one-two meetings, targeted to all radiographers (including local reference radiographers) in

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Patient Identification Number		Nipple in profile	Inframmary fold in internal quadrants and retromammary spaces	Inframmary fold in external quadrants and retromammary spaces	Symmetrical images	Absence of overlying artifacts	Absence of small artifacts	Compression => 5 decaNewtonh	Absence of internal/external glandular rotation		Nipple in profile	Symmetrical images	Absence of overlying artifacts	Absence of small artifacts	Compression => 5 decaNewtonh	Absence of upper/lower rotation	Pectoral muscle shadow to the nipple level	Complete visibility of the submammary sulcus	Partial visibility of the submammary sulcus profile	Score	Image quality category
	CC VIEW									**MLO VIEW**											
	R	0	0	0	0	0	0	0	0	R	0	0	0	0	0	0	0	0	0		
	L	0	0	0	0	0	0	0	0	L	0	0	0	0	0	0	0	0	0	0.00	Perfect
	R	1	0	0	0	0	0	0	0	R	0	0	0	0	0	0	0	0	0		
	L	0	0	0	0	0	0	0	0	L	0	0	0	0	0	0	0	0	0	1.00	Excellent
	R	0	0	0	1	1	0	0	0	R	1	0	0	0	0	0	0	0	0		
	L	0	0	0	0	0	0	0	0	L	0	0	0	0	0	0	0	0	0	1.60	Good
	R	0	0	0	0	0	0	0	1	R	0	0	0	0	0	0	1	1	0		
	L	0	0	0	0	0	0	0	1	L	0	0	0	0	0	0	1	0	0	3.25	Moderate
	R	1	0	0	0	0	0	0	0	R	0	0	0	0	0	0	0	1	1		
	L	1	0	0	0	0	0	0	0	L	0	0	0	0	0	0	0	1	1	4.00	Poor
Code		**A**	**B**	**B1**	**C**	**D**	**D1**	**E**	**F**		**A**	**C**	**D**	**D1**	**E**	**F**	**G**	**H**	**H1**		

Figure 2. Facsimile of a filled image quality assessment form, translated in English, being used in the Emilia-Romagna Region mammographic image quality review programme. CR, computed radiography; DR, direct radiography; CC, craniocaudal; MLO, mediolateral oblique; R, right; L, left.

order to discuss with them of their performance and of the most common technical errors; and an advanced course in which the IQ of the mammograms is reviewed interactively.

While first-level radiographers undergo these educational interventions, the two local reference radiographers select a new systematic sample of five mammography examinations per first-level radiographer, according to the same criteria as in the first round, and perform their review. In the case of discordant opinions, the mammograms are evaluated on-site by the programme head as an arbitration reading.

The programme monitor processes the new set of assessment forms and evaluates the changes occurring between the first and the second round. The results of both rounds of the programme are presented in a meeting of all staff engaged.

The Ethics Committee at the Romagna Cancer Institute of Meldola, Forlì, Italy was asked for ethics approval. The Committee granted a waiver as ethics approval is not required, because this project involves established and regular educational practices that are done according to a law from an Italian Regional Government and are targeted at institutional health care staff as part of the employment duties.

Results

In the 47 imaging facilities involved in the regional screening service, the annual number of two-view bilateral screening mammography examinations grew from 140,822 in 2008 (target age, 50–69 years) to 319,394 in 2014 (45–74 years) (+127%), unbalanced by an equal adjustment of the radiographer workforce and then roughly stabilised.

Table 2 shows the regional IQ distribution of the mammograms reviewed in 2010, 2012, 2016 and 2018 as compared with the quality objectives set by the 2006 European guidelines for breast cancer screening and diagnosis.[9] In 2012, the proportion of mammograms with a poor IQ rose from 0.6% to as much as 19.3%. This was paralleled by a substantial decrease of mammograms interpreted to have a moderate and, more important, a perfect level of IQ. Conversely, a generalised improvement was observed in both rounds of 2016 and, to an even greater extent, in the first round of 2018. In the second round of 2018, two opposite (albeit limited) variations occurred, that is, the ≥good category dropped slightly below the standard level of >85.0%, and the inadequate (repeat needed) category exceeded 2.0%

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versus a standard of <1.0%. These two observations warrant monitoring. Overall, however, the programme proved to be effective in maintaining the levels of IQ needed to meet current European standards.

Discussion

This programme fulfils some important theoretical requirements for an effective IQ review initiative.[16] With its background and long-standing experience, the steering committee offers a specific professional leadership to the participating radiographers. The committees operate on behalf of the Regional Department of Health and works in a supportive environment.

The experience gained in 2010–2015 was used to refine the programme model. In this way, the initiative has become more effective, more sustainable and more acceptable for participants. In its present form, the programme has been implemented in late 2016. Since then, it has been exported to five more administrative regions and healthcare districts of northern and southern Italy. The protocol has proved to be feasible in screening settings other than that of origin.

On an international scale, the variety of approaches proposed for IQ assessment in the area of mammography screening suggests that a widely accepted method to monitor and optimise the performance of radiographers has not been developed yet.[1,17] It remains necessary to disseminate and evaluate the methods and the results of all ongoing experiences. The programme described here is not designed to set up a central control system. It places the emphasis on motivating and training the radiographers and not on testing them or ranking them or certifying their competence. This strategy made it possible to face a rapid growth of over 125% in mammogram volume – a sort of natural experiment – with only a transient decrease in IQ.

Conclusion

In the new challenging scenario, the programme proved to be effective. The key to this result was that the programme places emphasis on motivating and training the radiographers. A successful IQ review initiative is one that encourages radiographers to participate with a positive and confident attitude.

Table 2. Participating screening centres and radiographers, number of mammography examinations and mammograms selected for review and image quality distribution in 2010, 2012, 2016 (after the programme assumed the current form) and 2018 in the Emilia-Romagna Region mammographic image quality review programme.

	2010*	2012†	2016, 1st round	2016, 2nd round	2018, 1st round	2018, 2nd round
Participating radiographers, n	181	182	187	195	183	171
Participating screening centres, n	12	11	11	11	11	9
Mammography examinations reviewed, n	905	910	935	975	915	855
Mammograms reviewed, n	3620	3640	3740	3900	3660	3420
IQ distribution, n (%)						
Inadequate (repeat needed) (standard, <1.0%)†	0 (0.0)	0 (0.0)	8 (0.9)	12 (1.2)	10 (1.1)	23 (2.7)
Poor	5 (0.6)	176 (19.3)	23 (2.5)	19 (1.9)	29 (3.2)	32 (3.7)
Moderate	309 (34.1)	170 (18.7)	138 (14.8)	118 (12.1)	93 (10.2)	103 (12.0)
Good	369 (40.8)	319 (35.1)	366 (39.1)	376 (38.6)	35 (38.8)	327 (38.2)
Excellent	0 (0.0)	173 (19.0)	318 (34.0)	367 (37.6)	367 (40.1)	318 (37.2)
Perfect	222 (24.5)	72 (7.9)	82 (8.8)	83 (8.5)	61 (6.7)	52 (6.1)
Categorised IQ distribution, %						
Poor + inadequate (standard, <3.0%)‡	0.6	19.3	3.3	3.2	4.3	6.4
Perfect + excellent + good (standard, >85.0%)‡	64.9	60.3	78.6	90.3	91.6	77.9
Perfect + excellent + good + moderate (standard, >97.0%)‡	99.4	80.7	96.7	96.8	95.7	93.6

IQ, image quality.
*One round only was conducted in order to accurately test the early protocol.
†One round only was conducted because part of the Emilia-Romagna Region was hit by an earthquake.
‡The standards for IQ distribution are the radiographic quality objectives put forth by the 2006 European guidelines for quality assurance in breast cancer screening and diagnosis.[9]

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Acknowledgements

Conflict of Interest

The authors declare non-conflict of interest.

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Risultati sommari

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Quality assurance (QA) in medical imaging

- Raccolta e valutazione sistematica di dati di servizio

- Identificazione delle performances insufficienti (inferiori agli standards)

- Decisioni (educazione, etc.)

- *"… QA is often considered judgemental and punitive .."*

- *"… a phylosophy …":* se si elimina ciò che non va, il resto è di qualità sufficiente

- … ma una qualità sufficiente non è la migliore qualità possibile

Un Editoriale

Journal of Medical Radiation Sciences

EDITORIAL

The role of quality improvement in radiography *J Med Radiat Sci* **68** (2021) 214–216

Quality assurance (QA) in medical imaging

Digital radiography reject analysis of examinations with multiple rejects: an Australian emergency imaging department clinical audit

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Un Editoriale

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Table 1. Frequency distribution of approved and rejected images each body part

	Approved images[†] (n (%))	Rejected images[‡] (n (%))	Multiple rejects[§] (n (%))	Total
Shoulder	419 (81.0%)	98 (19.0%)	15 (2.9%)	517
Clavicle	18 (78.3%)	5 (21.7%)	0	23
Humerus	54 (91.5%)	5 (8.5%)	0	59
Elbow	162 (82.7%)	34 (17.4%)	5 (2.6%)	196
Forearm	115 (92.7%)	9 (7.3%)	0	124
Wrist	328 (89.4%)	39 (10.6%)	5 (1.4%)	367
Hand	295 (95.8%)	13 (4.2%)	3 (1.0%)	308
Fingers/ thumb	84 (97.7%)	2 (2.3%)	0	86

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Table 3. Frequency of reasons for rejection

Reason for rejection	Number of rejects (
Positioning	692 (58.0%)
Anatomy cut-off	218 (18.3%)
Clothing artefacts	72 (6.3%)
Incorrect detector selected	51 (4.2%)
Poor inspiration	47 (3.9%)
Patient movement	33 (2.8%)
Under exposed	27 (2.3%)
Mechanical failure	17 (1.4%)
Detector artefacts	12 (1.0%)
Over exposed	5 (0.4%)
Motion blur	4 (0.3%)

Un Editoriale

Continuous quality improvement (CQI) in medical imaging

- **Identificazione di un processo che richiede un miglioramento**

- **Pianificazione di test e analisi**

- **Valutazione degli effetti dei provvedimenti presi**

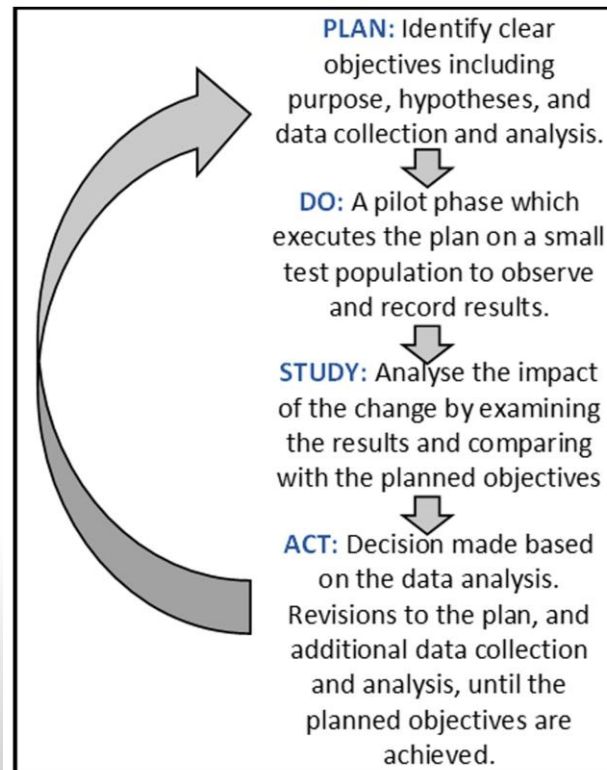- **Ripetizione continua per ottenere miglioramenti ulteriori**

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Continuous quality improvement (CQI) in medical imaging

Figure 1. PDSA or Deming Cycle.[7]

PLAN: Identify clear objectives including purpose, hypotheses, and data collection and analysis.

DO: A pilot phase which executes the plan on a small test population to observe and record results.

STUDY: Analyse the impact of the change by examining the results and comparing with the planned objectives

ACT: Decision made based on the data analysis. Revisions to the plan, and additional data collection and analysis, until the planned objectives are achieved.

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Continuous quality improvement (CQI) in medical imaging

This issue of JMRS also includes a study by Galli et al.[8] which involved an image quality review programme for mammography based on the 2006 European guidelines for QA in breast cancer screening and diagnosis. Interestingly, this longitudinal study did follow a CQI model where training and monitoring of entry-level and experienced radiographers developed the mammogram service and improved technical assessments of image quality.[8] This is a key example of an effective QA study for continuous quality improvement for sustaining a high standard of diagnostic imaging and performance of radiographers.

Dal sito dell'ONS

QUALITÀ TECNICA DELLE IMMAGINI MAMMOGRAFICHE: NUOVE TECNOLOGIE E FORMAZIONE

La pubblicazione dell'articolo di Vania Galli e colleghi sul *Journal of Medical Radiation Sciences* diventa occasione per un confronto sulla cultura del monitoraggio nei programmi di screening.

Il commento di Antonio Rizzo

- La dicotomia tra audit e miglioramento continuo è apparente: c'è sempre un legame indissolubile tra analisi dei dati e azioni volte al miglioramento continuo.

- Ciò si realizza al meglio attraverso il coinvolgimento attivo degli operatori, perché la qualità è la massima realizzazione della dignità professionale.

- Purtroppo, il lavoro sulla qualità non è istituzionalizzato: è considerato mero aggiornamento professionale anziché parte centrale del sistema sanitario.

➡ Esso era previsto nell'intesa Stato-Regioni per la creazione dei Centri di senologia, ma l'indicazione è stata largamente disattesa.

➡ La pubblicazione del manuale dello schema di garanzia di qualità europeo (ECIBC), che pure è datato in alcuni aspetti, può agire da stimolo.

- Bisogna pensare alla qualità dell'intero percorso della paziente, con l'integrazione dello screening nei Centri di senologia.

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Il commento di Stefano Pacifici

- Il sistema di valutazione della qualità mammografica PGMI è discusso.

- Va dato atto al gruppo TSRM dell'Emilia-Romagna di averlo migliorato, in particolare con l'introduzione di sotto-criteri.

- Tuttavia, questo ha aumentato la soggettività dell'interpretazione, che richiede istruttori esperti e una lunga curva di apprendimento.

- Nelle realtà dove il personale tecnico non è sufficientemente dedicato, il metodo può presentare un'efficacia bassa rispetto ai costi.

- Oggi sarebbe anacronistico sviluppare questi modelli, già sostituiti da software che sfruttano l'intelligenza artificiale.